APPENDIX XXIV

Serial No.: 09/520,032

Docket No.: 49933US031

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1. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) cert. denied, 480 U.S. 947 (1987).
2. In re Hoeksema, 399 F.2d 269, 158 U.S.P.Q. 596 (CCPA 1968).
3. M.P.E.P. § 2121.01.
4. M.P.E.P. § 2141.01.
5. In re Wesslau, 353 F.2d 238, 147 U.S.P.Q. 391 (CCPA 1965).
6. Bausch & Lomb, Inc. v. Barnes-Hind/Hycrocurve, Inc., 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986) cert. denied, 484 U.S. 823 (1987), on remand, 10 U.S.P.Q. 2d 1929 (N.D. Calif. 1989).
7. In re Gorman, 933 F2d 982,18 U.S.P.Q.2d 1885 (Fed. Cir. 1991).
8. In re Dow Chem., 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

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Hybritech Incorporated v. Monoclonal Antibodies, Inc.

U.S. Court of Appeals Federal Circuit
231 USPQ 81

Decided September 19, 1986
No. 86-531

Headnotes

PATENTS

1. Patentability/Validity -- Date of invention -- Conception (§ 115.0403)

Federal district court's finding that evidence was lacking as to when, before May 1980, claimed invention of using monoclonal antibodies in "sandwich" assays was conceived by patent holder, is clearly erroneous, in view of evidence demonstrating patent holder's earlier efforts in developing claimed invention by using prior art technology to produce necessary monoclonal antibodies in diagnostic sandwich assay kits, in view of evidence demonstrating that exploiting monoclonal antibodies for use in sandwich assays was one of patent holder's major objectives, and in view of laboratory notebooks and research program that fully corroborate testimonial evidence of conception, since such evidence clearly supports holding that patent holder conceived claimed invention before patent challenger and that patent challenger's work is not prior art.

2. Patentability/Validity -- Anticipation -- Identity of elements (§ 115.0704)

Prior art work that involved "sandwich" assay to extent that antigen was sandwiched between two monoclonal antibodies, but that did not involve detecting presence of or quantitating antigen, did not anticipate claimed invention, since it did not meet its every element.

3. Patentability/Validity -- Obviousness -- Relevant prior art -- Particular inventions (§ 115.0903.03)

Articles which "predicted" widespread use of monoclonal antibodies but which are dated well after patented

nonoclonal assay's date of conception and within one year of its filing date, are not prior art, nor should earlier articles vhich discussed production of monoclonal antibodies, although clearly prior art, have been relied upon to establish ›bviousness of trying monoclonal antibodies of particular affinity in "sandwich" immunoassay that detects presence of ›r quantitates antigen, since such articles do not suggest how that end may be accomplished, and since "obvious to try" s improper consideration in adjudicating obviousness issue.

4. Patentability/Validity -- Obviousness -- Commercial success (§ 115.0908)

Trial court's finding that "sudden availability" of monoclonals was reason for commercial success of patented liagnostic kits is clearly erroneous, in view of evidence demonstrating that at least three years passed between time nonoclonal antibodies were available in adequate supply and time patent holder began selling its kits.

5. Patentability/Validity -- Specification -- Claim adequacy (§ 115.1109)

Federal district court erred in holding that claims for monoclonal assay are indefinite because antibody affinity cannot ›e estimated with any consistency, since calculating affinity was known in art at time of filing, and since such claims easonably apprise those skilled in art and are as precise as subject matter permits, even though calculations are not ›recise or "standard."

Particular patents -- Assays

4,376,110, David and Green, Immunometric Assays Using Monoclonal Antibodies, holding of invalidity reversed.

Case History and Disposition:

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Appeal from District Court for the Northern District of California, Conti, J.; 227 USPQ 215 .

Action by Hybritech Incorporated, against Monoclonal Antibodies, Inc., for patent infringement. From judgment for defendant, plaintiff appeals. Reversed and remanded.

Attorneys:

Douglas E. Olson, and Lyon & Lyon, both of Los Angeles, Calif. (James W. Geriak and Bradford J. Duft, both of Los Angeles, Calif., on the brief) for appellant.

David J. Brezner, and Flehr, Hohback, Test, Albritton & Herbert, both of San Francisco, Calif. (Barry E. Britschneider and Herbert I. Cantor, both of Washington, D.C., of counsel) for appellee.

Judge:

Before Rich, Davis, and Smith, Circuit Judges.

Opinion Text

Opinion By:

Rich, Circuit Judge.

This appeal is from the August 28, 1985, decision of the United States District Court for the Northern District of California, 623 F.Supp. 1344, 227 USPQ 215, in favor of defendant Monoclonal Antibodies, Inc. (Monoclonal) holding that all 29 claims of plaintiff's patent No. 4,376,110 entitled "Immunometric Assays Using Monoclonal Antibodies" ('110 patent), issued to Dr. Gary S. David and Howard E. Greene and assigned to Hybritech Incorporated Hybritech), are invalid as anticipated under 35 USC 102(g), for obvious

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ness under §103, and under §112 first and second paragraphs. We reverse and remand.

Background

Vertebrates defend themselves against invasion by microorganisms by producing antibodies, proteins which can complex with the invading microorganisms and target them for destruction or removal. In fact, any foreign molecule of sufficient size can act as a stimulus for antibody production. Such foreign molecules, or antigens, bear particular sites or epitopes that represent antibody recognition sites. B cell lymphocytes, the cells that actually produce antibodies, recognize and respond to an epitope on an antigen by reproducing or cloning themselves and then producing antibodies specific to that epitope. Even if the antigen is highly purified, the lymphocytes will produce antibodies specific to different epitopes on the antigen and so produce antibodies with different specificities. Furthermore, because the body is exposed to many different antigens, the blood of a vertebrate will contain antibodies to many different antigenic substances.

Scientists and clinicians have long employed the ability of antibodies to recognize and complex with antigens as a tool to identify or label particular cells or molecules and to separate them from a mixture. Their source of antibodies has been primarily the serum separated from the blood of a vertebrate immunized or exposed to the antigen. Serum, however, contains a mixture of antibodies directed to numerous antigens and to any number of epitopes on a particular antigen. Because such a mixture of antibodies arises from many different clones of lymphocytes, it is called 'polyclonal."

Recent technological advances have made it possible to isolate and cultivate a single clone of lymphocytes to obtain a virtually unlimited supply of antibodies specific to one particular epitope. These antibodies, known as "monoclonal antibodies" because they arise from a single clone of lymphocytes, are produced by a relatively new technology known as the hybridoma. Hybridomas are produced by fusing a particular cancer cell, the myeloma cell, with spleen cells from a mouse that has been injected or immunized with the antigen. These fusions are isolated by transferring them to a growth fluid that kills off the unfused cancer cells, the unfused spleen cells dying off by themselves. The fused hybrid spleen and myeloma cells, called hybridomas, produce antibodies to the antigen initially injected into the mouse. The growth fluid containing the hybridomas is then diluted and put into individual test tubes or wells so that there is only one hybridoma per tube or well. Each hybridoma then reproduces itself and these identical hybridomas each produce identical monoclonal antibodies having the same affinity and specificity. In this way, a virtually unlimited supply of identical antibodies is created, directed to only one epitope on an antigen rather than, as with polyclonal antibodies, to many different epitopes on many different antigens.

In addition to the specificity of antibodies to particular epitopes discussed above, antibodies also have a characteristic "sensitivity," the ability to detect and react to antigens. Sensitivity is expressed in terms of "affinity:" the greater an antibody's ability to bind with a particular antigen, the greater the antibody's affinity. The strength of that antibody-antigen bond is in part dependent upon the antibody's "affinity constant," expressed in liters per mole, for the antigen.

Immunoassays, the subject matter of the '110 patent are diagnostic methods for determining the presence or amount of antigen in body fluids such as blood or urine by employing the ability of an antibody to recognize and bind to an antigen. Generally, the extent to which the antibody binds to the antigen to be quantitated is an indication of the amount of antigen present in the fluid. Labelling the antibody or, in some cases, the antigen, with either a radioactive substance, I^{125}, or an enzyme makes possible the detection of the antibody-antigen complex. In an extreme case, where

ıe fluid sample contains a very low level of the antigen, binding might not occur unless the antibodies selected or screened" for the procedure are highly sensitive.

n the case of a "competitive" immunoassay, a labelled antigen reagent is bound to a limited and known quantity of ntibody reagent. After that reaction reaches equilibrium, the antigen to be detected is added to the mixture and ompetes with the labelled antigen for the limited number of antibody binding sites. The amount of labelled antigen eagent displaced, if any, in this second reaction indicates the quantity of the antigen to be detected present in the fluid ample. All of the antigen attached to the antibody will be labelled antigen if there is no antigen in the test fluid ample. The advantage of this method is that only a small amount of antibody is needed, its drawback, generally, that ıe system must reach equilibrium, and thus produces results slowly.

n the case of a "sandwich" assay, otherwise known as an immunometric assay, the latter being a term coined by Dr. awton Miles in 1971, a quantity of unlabelled antibody reagent is bound to a solid support surface such as the inside vall of a test tube containing a complex of the fluid sample containing the

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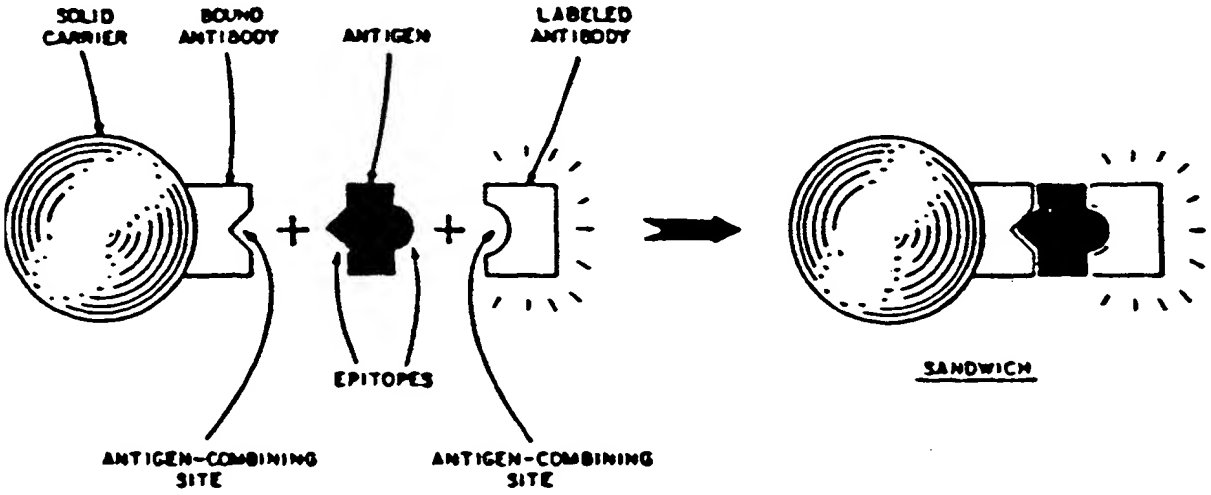
ntigen to be detected and a labelled *antibody* reagent. The result is an insoluble three part complex referred to as a andwich having antibody bread and antigen filling. This figure is illustrative of the sandwich concept:



The advantage of the sandwich assay is that it is fast and simple, its drawback that enormous quantities of antibodies ıre needed.

Hybritech

Hybritech, started in 1978 and joined thereafter by coinventors Green and Dr. David, has, since 1979, been in the ıusiness of developing diagnostic kits employing monoclonal antibodies that detect numerous antigens and thus a ıroad range of conditions such as pregnancy, cancer, growth hormone deficiency, or hepatitis. Examples of antigens nclude influenza viruses, immunoglobulin E (IgE) which indicates allergic reaction, human chorionic gonadotropin HCG) which indicates pregnancy, and prostatic acid phosphatase (PAP) which indicates prostate cancer, to name a ew. Dr. Adams, a business-experienced scientist, joined the company in May 1980 as head of research and levelopment. The '110 patent, application for which was filed August 4, 1980, issued March 8, 1983, with claims lefining a variety of sandwich assays using monoclonal antibodies. Claim 19, apparently the broadest of the twenty-ıine in the patent, is directed generally to a sandwich assay and reads (emphasis ours):

19. In *an immunometric assay* to determine the presence or concentration of an antigenic substance in a sample of a luid comprising forming a ternary complex of a first labelled antibody, said antigenic substance, and a second antibody aid second antibody being bound to a solid carrier insoluble in said fluid wherein the presence of the antigenic ubstance in the samples is determined by measuring either the amount of labelled antibody bound to the solid carrier ır the amount of unreacted labelled antibody, *the improvement comprising* employing monoclonal antibodies having an

ffinity for the antigenic substance of at least about 10 ^{8}liters/mole for each of said labelled antibody and said antibody ound to a solid carrier.

:laim 1, directed particularly to a reverse sandwich assay, explained infra, reads:

. A process for the determination of the presence of [sic, or] concentration of an antigenic substance in a fluid omprising the steps:

a) contacting a sample of the fluid with a measured amount of a soluble first monoclonal antibody to the antigenic ubstance in order to form a soluble complex of the antibody and antigenic substance present in said sample, said first nonoclonal antibody being labelled;

b) contacting the soluble complex with a second monoclonal antibody to the antigenic substance, said second nonoclonal antibody being bound to a solid carrier, said solid carrier being insoluble in said fluid, in order to form an nsoluble complex of said first monoclonal antibody, said antigenic substance and said second monoclonal antibody ound to said solid carrier;

c) separating said solid carrier from the fluid sample and unreacted labelled antibody;

d) measuring either the amount of labelled antibody; associated with the solid carrier or the amount of unreacted abelled antibody; and

e) relating the amount of labelled antibody measured with the amount of labelled antibody measured for a control ample prepared in accordance with steps (a)-(d), said control sample being known to be free of said anti-genic ubstance, to determine the presence of antigenic substance in said fluid sample, or relating the amount of labelled ntibody measured with the amount of labelled antibody measured for samples containing known amounts of antigenic ubstance prepared in accordance with steps (a)-(d) to determine the concentration of antigenic substance in said fluid ample, the first and second monoclonal antibodies having an affinity for the antigenic substance of at least about 10 liters/mole.

The District Court Decision

Hybritech sued Monoclonal March 2, 1984, for damages and an injunction alleging that the manufacture and sale of Monoclonal's diagnostic kits infringed the '110 patent. Trial without a jury began on August 5, 1985, and concluded August 23, 1985, thirty witnesses having been heard and over 2,000 pages of transcript generated. The district court produced the reported opinion, findings, and con

clusions, which use nearly verbatim Monoclonal's *pre-trial* brief and *pre-trial proposed* findings of fact and conclusions of law, in three days, in support of the judgment now on appeal.

The district court held that the claimed subject matter of the '110 patent was neither conceived nor actually reduced to practice before May 1980, and was anticipated under §102(g) by the actual reduction to practice of the invention by Drs. Uotila and Ruoslahti at the La Jolla Cancer Research Foundation (LJCRF) as early as November of 1979 and by the actual reduction to practice of the invention by Drs. Oi and Herzenberg (Oi/Herzenberg work) at the Stanford University Laboratory as early as July 1978, later published in December of 1979.

The district court also held the claims of the '110 patent invalid for obviousness from the Oi/Herzenberg work in view of (1) a February 1979 article by M. E. Frankel and W. Gerhard (Frankel article) which discloses high-affinity monoclonal antibodies, and apparently in view of numerous other references including (2) the work of Nobel Prize winners G. Kohler and C. Milstein disclosing a Nobel Prize-worthy method for producing monoclonal antibodies in vitro (outside the body) published in an August 7, 1975, article; (3) U.S. Patent No. 4,244,940 issued to Jeong et al. disclosing a simultaneous polyclonal assay (Jeong), U.S. Patent No. 4,098,876 to Piasio et al. disclosing a reverse polyclonal sandwich assay (Piasio), U.S. Patent No. 4,016,143 to Schurrs et al. disclosing a forward polyclonal sandwich assay (Schurrs); (4) a July 1979 publication by A. C. Cuello et al. disclosing the use of monoclonal

ntibodies in competitive assays; and (5) eight articles dated between January 1979 and March 6, 1980, "predicting" hat monoclonal antibodies would be used in future immunoassays. 1

The district court also invalidated the patent on various grounds based on 35 USC 112, first and second paragraphs, as ıereinafter discussed.

A. *The References*

1. *Kohler and Milstein's Nobel Prize-Winning Work: Producing Monoclonal Antibodies In Vitro For the First Time*

n early immunoassay work, polyclonal antibodies produced in vivo (in the body) in mice were used to bind with the ıntigen to be detected in the body fluid sample. Mice were immunized by injection with antigen so that the ymphocytes in their bodies produced antibodies that attacked the injected antigen. Those polyclonal antibodies were vithdrawn from the animal's blood and used in immunoassays. The major problem was that when the mice's immune ;ystems changed or the mice died, the antibodies changed or died too; supply was limited and uncertain.

As the examiner was aware, Kohler and Milstein developed a technique not only for producing antibodies in vitro, ndependent of a living body, thus eliminating dependence on a particular animal, but for in vitro production of nonoclonal antibodies by hybridomas, discussed in the Background section, supra.

Given that sandwich assays require enormous amounts of antibodies, companies like appellant and appellee, which ıtilize monoclonal antibodies for sandwich assays, would not be in business were it not for the work of Kohler and Milstein.

2. *The Work of Drs. Ruoslahti, Uotila, and Engvall at the La Jolla Cancer Research Foundation (LJCRF) in 1979 and 1980*

Dr. Ruoslahti performed mostly competitive immunoassays using polyclonal antibodies to alphafetoprotein (AFP) ıntigens at the City of Hope since 1970. Dr. Uotila joined him in late 1978 to perform immunoassays using nonoclonal antibodies to AFP. After producing monoclonal antibodies to AFP and performing competitive radio ımmunoassays (RIA -- a competitive assay that uses a radioactive label) with monoclonal antibodies at the City of Hope in mid-1979, Drs. Ruoslahti, Uotila and Engvall left LJCRF.

In the fall of 1979, September or October according to Dr. Uotila, discussion and work began on using monoclonal ıntibodies to AFP in a sandwich assay. Dr. Uotila, the principal researcher in this particular endeavor, generated six notebooks while at the City of Hope and LJCRF. The next-to-last page of notebook four contained a note to Dr. Uotila from Dr. Ruoslahti reading:

Sometime you should enzyme label a good monoclonal antibody so that you can set up a sandwich assay. If you use two monoclonal antibodies, you may be able to do the assay with a single incubation, since the monoclonal antibodies are likely to be

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directed against different determinants and not compete with one another.

Although Dr. Uotila's notebook pages were, for the most part, unsigned, undated, and uncorroborated, Dr. Ruoslahti's testimony, placed the date of this note at about October 1979 by referring to the first pages of notebook five which were dated in early November 1979. Dr. Ruoslahti testified that one curve on one graph on page 43D of notebook five showed a successful simultaneous sandwich assay using monoclonal antibodies about November 5, 1979, although no data supporting that graph could be found elsewhere in the notebook. He further testified that the affinity of the monoclonal antibodies used for that test was not calculated until 1980 but that the raw data necessary for that calculation was generated in 1979.

Dr. Uotila stated in her deposition (she did not testify at trial) that she started work on a sandwich assay using

nonoclonal antibodies between October 4 and the end of that month, 1979, and that she could not remember the procedure used nor was there enough information in her notebook, including page 43D, to refresh her memory. She did remember, although she continued work on this assay because the tests did not yield repeatedly good curves without which she would not publish her work, that the assay on page 43D was successful. Dr. Engvall testified about a discussion of Dr. Uotila's monoclonal antibody work with her while at the City of Hope and about first performing a sandwich assay after arriving at LJCRF in 1979.

3. *The Work of Drs. Oi and Herzenberg at the Stanford University Laboratory in 1978 Published in December 1979*

Drs. Oi and Herzenberg used monoclonal antibodies to "map" epitopes or determine the number and location of different antibody binding sites on a known quantity of IgE antigen by attaching to it an antibody bound to a carrier and exposing that antigen to other monoclonal antibodies. The antibodies either attached to epitopes on the antigen or were blocked from doing so by the other monoclonal antibodies, depending on the location and number of epitopes; if the epitopes on the antigen were too close together and the number of antibodies too great, few antibodies would bind to the antigen. Hybritech points out that both Dr. Herzenberg and Dr. Oi testified that *their work did not involve determining the presence or quantity of antigen,* that they had no idea what the affinities of the monoclonal antibodies used were, and that those values were never calculated.

One unsigned, unwitnessed page from three large laboratory notebooks, which Hybritech argues is insufficient because it does not identify the chemical reagents or protocol used, was relied on by Monoclonal to establish actual reduction to practice of the Oi/Herzenberg work in 1978 to establish a case of §102(g) prior invention by another. The district court agreed with Monoclonal that the Oi/Herzenberg work anticipated the claimed invention and, in addition, combined this work with the Frankel publication to hold that the claimed subject matter was obvious under §103.

4. *The Frankel Article: Monoclonal Antibodies Having Affinities of 10 ^{9}liters/mole*

Frankel describes an RIA (radioimmunoassay) method for the rapid determination of affinity constants for monoclonal antibodies produced from hybridomas. The article states that the assay used is applicable only to antibodies with binding constants of about 10 ^{10}liters/mole and discloses the binding constants for antibodies to several closely related strains of influenza virus.

The district court found that Frankel disclosed monoclonal antibodies having the affinity constants claimed in the '110 patent, 10 ^{8}to over 10 ^{9}liters/mole.

5. *The Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

Cuello, dated July 1979, states that it describes the usefulness of monoclonal antibodies in the characterization and localization of neurotransmitters such as Substance P, a peptide clearly associated with the transmission of primary sensory information in the spinal cord. The article discloses producing monoclonal antibodies from hybrid myelomas (hybridomas), their use in conventional radioimmunoassay techniques, and the benefits from doing so which flow from the ability to derive permanent cell lines capable of continuous production of highly specific antibodies.

The district court found that the examiner twice rejected all of the claims of the '110 patent based on Cuello alone or in combination with the Jeong, Piasio, and Schurr references which disclose various sandwich assays using polyclonal antibodies. The court also found that the examiner allowed the claims after they were amended to include the 10 ^{8}affinity limitation and after Richard Bartholomew, a Hybritech employee, submitted an affidavit alleging the advantages of using monoclonal rather than polyclonal antibodies in sandwich assays.

Apparently based on the testimony of Monoclonal's expert witness Judith Blakemore, a named inventor of the Jeong patent, manager of antibody programs at Bio-Rad Laboratories from 1975 to 1982, and currently manager of monoclonal antibody therapeutics at Cetus Corporation, a Hybritech competitor in immunoassay diagnostics, the district court stated

hat the "reasons for allowance were not well-founded because (1) the alleged advantages were expected as naturally lowing from the well-known natural characteristics of monoclonal antibodies . . .; (2) . . . were not significant . . .; or 3) were at best minor," although they were "argued to the examiner as if they were" important. These were Monoclonal's words from its pretrial submission adopted by the court.

6. *The References That "Predicted" the Use of Monoclonal Antibodies in Immunoassays*

The district court stated, again in Monoclonal's words, that "it is of the utmost importance" that the advantages of nonoclonal antibodies were "predicted by a number of authorities," eight to be exact, not important enough to list here, ıfter the Kohler and Milstein discovery and after monoclonal antibodies became available.

B. *The Claimed Subject Matter of the '110 Patent*

Hybritech argues that the district court's determination that there is no credible evidence of conception or reduction to ɔractice of the '110 invention before May 1980 is error because Dr. David's laboratory notebooks, Nos. 21 and 24, :learly show successful sandwich assays using monoclonal antibodies in August, September, and October of 1979. At he least, argues Hybritech, the invention was conceived in January of 1979, long before Drs. Ruoslahti, Engvall, and Jotila began work on a sandwich assay using monoclonal antibodies, and diligence was thereafter exercised until :onstructive reduction to practice occurred by the filing of the '110 patent application on August 4, 1980.

Dr. David and Greene testified that pages 2118 to 2122 of Dr. David's notebook, dated January 4, 1979, and witnessed January 30, 1979, disclose the generic conception of the invention in the context of the physical support structure used o carry out a sandwich assay, and Dr. David testified on redirect that (1) Page 1128 of notebook 21, dated May 27, 1979, recorded an early attempt at a sandwich assay that failed, (2) on August 3, 1979, as recorded at page 1166, a sandwich assay using monoclonal antibody 068 attached to a solid carrier, a radio-labelled 068 antibody, and a hepatitis ıntigen from an Abbott Labs polyclonal competitive assay kit was successfully performed, and (3) a sandwich assay ısing a bound 259 antibody, a radio-labelled 068 antibody, and a hepatitis antigen was successfully performed on September 21, 1979. Hybritech also urges that work in October 1979 directed to determining whether certain nonoclonal antibodies were recognizing the same or different determinants, was a reduction to practice.

Monoclonal points out that these notebook pages do not expressly state that monoclonal antibodies of 10 ^{8}liters/mole ıffinity were used in a sandwich assay and that the May, August, and September notebook entries were not witnessed ıntil about the time Dr. Adams, experienced in patent matters, joined Hybritech and advised its researchers on properly :ecording laboratory work. They therefore claim that actual reduction to practice was not shown before May 1980.

OPINION

I. *Review Under Rule 52(a) Fed. R. Civ. P.*

Rule 52(a) "ensures care in the preparation of an opinion . . . and provides appellate courts with the benefit of the District Court's insights into a case," *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309 318, 227 USPQ 766, 772 (Fed. Cir. 1985) (Harvey, Senior District Judge, concurring) by requiring a district court to "find the facts specially and state separately its conclusions of law thereon." With the exception of the first eight paragraphs, the first half of the district court's opinion here is Monoclonal's *pretrial* brief and the last three pages of the opinion are Monoclonal's *pretrial* findings of fact and conclusions of law. The district court adopted the above documents virtually verbatim, with the exception of portions of each concerning inequitable conduct and noninfringement, apparently without inviting a response from Hybritech, resulting in a repetitious (as the district court admitted in the opinion), sometimes internally inconsistent, and hard to follow opinion that presents us with a difficult task in gleaning the basis for many of the conclusions. For some of the findings, submitted before trial, no supporting evidence was introduced at trial.

The Supreme Court, in *Anderson v. City of Bessemer City, N.C.*, 105 S.Ct. 1504 (1985), strongly criticized the practice of "verbatim adoption of findings of fact prepared by prevailing parties, particularly when those findings have taken the form of conclusory statements unsupported by citation to the record." *Anderson*, supra at 1511. This court also has cautioned against the adoption of findings, especially when proposed by a party before trial, as here, and stated that the likelihood of clear error in those findings increases in such a situation. *Lindemann Maschinenfabrik v. American Hoist*

ınd Derrick, 730 F.2d 1452, 1457, 221 USPQ 481, 485 (Fed. Cir. 1984).

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Notwithstanding our misgivings about whether the findings in this case, prepared before any evidence was introduced, satisfy the objectives of Rule 52(a) -- a carefully prepared opinion providing the reviewing court with the benefit of the district court's *reasoned insights* into the case -- those findings are the district court's and may be reversed only if clearly erroneous. *See Anderson,* supra, at 1511; *Lindemann,* 730 F.2d at 1457, 221 USPQ at 485.

'A finding is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.,* 333 U.S. 364, 395 (1948). "This standard plainly does not entitle a reviewing court to reverse the finding of the trier of fact simply because it is convinced that it would have decided the case differently." *Anderson,* supra, at 1511. In other words, "if the district court's account of the evidence is plausible in light of the record viewed in its entirety" or "where there are two permissible views of the evidence," the factfinder cannot be clearly erroneous. *Anderson,* supra, at 1511 (quoting *United States v. Yellow Cab Co.,* 338 U.S. 338, 342 (1949)). This is so, stated the Court in dictum, *see Anderson,* supra, at 1516 (Blackmun, J., concurring), even when the district court's findings rest on physical or documentary evidence or inferences from other facts and not on credibility determinations. *See also* Rule 52 (a) Fed. R. Civ. P. (as amended Aug. 1, 1985). If the latter are involved, "Rule 52 demands even greater deference to the trial court's findings" but a trial judge may not "insulate his findings from review by denominating them credibility determinations"; if documents or objective evidence contradict the witness' story, clear error may be found even in a finding purportedly based on a credibility determination. *Anderson,* supra, at 1512-13. We proceed in light of all these principles.

II. *Presumption of Validity*

Under 35 USC 282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. *See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc.,* 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984). Notwithstanding that the introduction of prior art not before the examiner may facilitate the challenger's meeting the burden of proof on invalidity, the presumption remains intact and on the challenger throughout the litigation, and the clear and convincing standard does not change. *See, e.g., Jervis B. Webb Co. v. Southern Systems, Inc.,* 742 F.2d 1388, 1392 & n.4, 222 USPQ 943 , 945 & n.4 (Fed. Cir. 1984). The only indication that the district court recognized the presumption of validity and its proper application was its statement that "[t]he key issue in this case is whether the defendant has overcome the presumption of nonobviousness." That statement, however, speaks only part of the truth; the presumption of validity goes to validity of the patent in relation to the patent statute *as* a *whole,* not just to nonobviousness under Section 103.

III. *Prior Invention of Another, 35 USC 102(g)*

Section 102(g) states that a person shall be entitled to a patent unless "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it." Section 102(g) "relates to prior inventorship by another in this country" and "retains the rules governing the determination of priority of invention . . . . " *Kimberly-Clark Corp. v. Johnson & Johnson,* 745 F.2d 1437, 1444, 223 USPQ 603, 606 (Fed. Cir. 1984) (quoting P.J. Federico, *Commentary on the New Patent Act,* 35 USCA page 1, at 19 (1954)). Section 102(g) says: "In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

Reduction to practice, and conception as well, is a legal determination subject to review free of the clearly erroneous standard. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd,* 731 F.2d 831, 837, 221 USPQ 561, 565-66 (Fed. Cir. 1984); *D.L. Auld Co. v. Chroma Graphics Corp.,* 714 F.2d 1144, 1151, 219 USPQ 13, 18 (Fed. Cir. 1983). Findings of fact supporting that legal conclusion, are, of course, reviewed under the clearly erroneous standard.

Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." 1 *Robinson On Patents* 532 (1890); *Coleman v. Dines,*

'54 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985). Actual reduction to practice requires that the claimed nvention work for its intended purpose, *see, e.g., Great Northern Corp. v. Davis Core & Pad Co.*, 782 F.2d 159, 165, '28 USPQ 356, 358, (Fed. Cir. 1986), and, as has long been the law, constructive reduction to practice occurs when a)atent application on the claimed invention is filed. *Weil v. Fritz*, 572 F.2d 856, 865 n.16,

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96 USPQ 600, 608 n.16 (CCPA 1978) (citing with approval *Automatic Weighing Machine Co. v. Pneumatic Scale Corp.*, 166 F. 288 (1st Cir. 1909)).

1] After a review of the record in its entirety, including the numerous corroborating Hybritech laboratory notebooks, nternal documents, and pertinent testimony, we hold clearly erroneous the district court's finding that there is no clear)r corroborated evidence "with regard to when before May 1980, the idea of actually using monoclonals in sandwich ıssays" was conceived or, more properly, of when the *claimed invention* was conceived, and therefore reverse the :ourt's holding, as a matter of law, that Hybritech's inventors did not conceive the claimed invention before May 1980.

Hybritech's claim of conception, generally, is evidenced by the sometimes sparsely documented work of a start-up :ompany whose first small advances evolved into the myriad activities of a mature company with efforts directed oward developing the claimed invention by first employing the Kohler and Milstein technology to produce the ıecessary monoclonal antibodies and using those antibodies in diagnostic sandwich assay kits. There is no doubt that :xploiting monoclonal antibodies for use in sandwich assays was one of the major objectives of Hybritech. In a letter o Pharmacia Fine Chemicals dated April 26, 1979, Greene, in responding to Pharmacia's interest in Hybritech's)roducts, outlined the latter's "efforts to bring the exciting new hybridoma technology into routine medical use" and its :xploration of "several intriguing concepts for which monoclonals may open up new immunodiagnostic techniques ıeretofore infeasible with animal serums." Although company minutes in early 1979 contain little about the claimed ;ubject matter and some of the discussions thereon, such as Greene's and Dr. Adams' conversation about monoclonal ;andwich assays when the former was trying to woo Dr. Adams to join Hybritech were unrecorded, the Hybritech aboratory notebooks and the nature of Hybritech's research program fully corroborate the testimonial evidence of :onception and thus clearly support our holding that Hybritech conceived the claimed invention before LJCRF.

Dr. David's January 1979 notebook describes, in detail, as explained by Greene and Dr. David at trial, a nylon ıpparatus that undoubtedly could be used for performing a sandwich assay using monoclonal antibodies, although Dr. David testified on cross-examination that at that time Hybritech had not yet developed any monoclonal antibodies, ncluding attaching one of the reagents to a solid carrier ring, contacting that ring with a fluid sample in a microtiter)late well, adding a labelled reagent to the well after rinsing, and then "counting" or measuring the amount of either the abelled or unlabelled reagent after a prescribed time and second rinsing. The notebook then describes the procedure 'or detecting an antibody "(a-x)" to an antigen "(x)" complete with diagrams and text, both illuminated by Dr. David at rial. The notebook further states, "Alternatively, if one wished to quantitate an antigen, y, the identical procedure would be followed, except that reagents would be reversed, i.e. the reaction would be:" and there follows a clear llustration of an antibody attached to a solid carrier reacting with an antigen to form a complex, and that complex 'eacting with a second labelled antibody. The notebook was signed by Dr. David on January 4, 1979, and witnessed ınd signed on January 30 of the same year by Dr. Curry, the first cell biologist hired at Hybritech to set up the ıybridoma production program.

Dr. David testified on direct that monoclonal antibodies were developed in the following months: antigens were)urchased from outside sources and purified before being injected into mice; the spleen cells from those mice were 'used with myelomas; and the resultant hybridomas were separated into well plates for development, and a 'adioimmunoassay procedure was carried out to determine the affinity of the antibodies.

The May 1979 failed sandwich assay, witnessed in May 1980, corroborates Dr. David's testimony that a polyclonal ıntibody bound to a solid carrier and a labelled monoclonal antibody were used in a sandwich assay with an antigen 'rom Abbott Labs' Ausria polyclonal diagnostic kit for hepatitis. No binding was detected.

Dr. David testified about the experiment documented in the August 1979 notebook, a sandwich assay with a hepatitis ıntigen from an Abbott Labs Ausria kit with two Hybritech 068 monoclonal antibodies, one attached to a solid carrier

ead and the other labelled; the purpose of the experiment was to quantitate the antigen. The notebook corroborates Dr. David's testimony that the test was positive and lists the counts per minute of the labelled antibody. Defendant Monoclonal's expert Ciotti testified about this experiment:

Also, of course, it is limited to -- it is limited to hepatitis antigen. And without a generic conception, it would just be merely a -- if it did work for its intended purpose -- which I would assume for purposes of discussion -- it *would be a reduction to practice of one embodiment.* And without a corresponding generic conception, I don't think it would be held to be the making of the invention in

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terms of, for instance, in claim 19. [Emphasis ours.]

Dr. David further testified that the September 21, 1979, record in David's notebook, witnessed months later, shows a reverse sandwich assay using a bound 259 monoclonal antibody and a labelled 068 monoclonal antibody with a hepatitis antigen with results confirmed by a dose response curve. 2 Hybritech further alleges that a laboratory notebook page dated October 1979 is a reduction to practice of the claimed invention but fails to cite any related testimony or other evidence in support thereof.

Finally, the record shows that the claimed affinity limitation "of at least about 10^8 liters/mole" was determined and appreciated during the course of the development of the claimed subject matter. Dr. David and Dr. Adams separately testified that the screening procedures used by Hybritech ensured that only monoclonal antibodies having at least 10 liters/mole affinity would be used in assays. An October 1979 internal memorandum from Greene to the staff states "To improve comparisons we will express all affinities to the base ten to the eighth which represents the lower end of the useable range."

We are left with the definite and firm conviction that a mistake has been committed because the district court's account of the evidence that "there was no credible evidence of conception before May 1980" is insupportable. There is such evidence. The laboratory notebooks, alone, are enough to show clear error in the findings that underlie the holding that the invention was not conceived before May 1980. That some of the notebooks were not witnessed until a few months to one year after their writing does not make them incredible or necessarily of little corroborative value. Admittedly, Hybritech was a young, growing company in 1979 that failed to have witnesses sign the inventors' notebooks contemporaneously with their writing. Under a reasoned analysis and evaluation of all pertinent evidence, however, we cannot ignore that Hybritech, within a reasonable time thereafter, prudently had researchers other than those who performed the particular experiments witness the notebooks in response to Tom Adams' advice. The notebooks clearly show facts underlying and contemporaneous with conception of the claimed invention and in conjunction with the testimony of Dr. David and Greene, and others, are altogether legally adequate documentary evidence, under the law pertaining to conception, of the formation in the minds of the inventors of a definite and permanent idea of the complete and operative invention as it was thereafter applied in practice. We thus are not moved by Monoclonal's argument that the findings of fact underlying conception are based on credibility determinations and are more sacrosanct than usual. *See Anderson,* supra, at 1512-13.

1. *LJCRF Is Not Prior Art*

Hybritech laboratory notebooks and the uncontradicted testimony of Dr. David and Mr. Greene show that development of the claimed invention proceeded diligently through the rest of 1979 and 1980, there being absolutely no evidence of record nor even argument by Monoclonal that Hybritech was not diligent in its efforts to reduce to practice the claimed invention during the period January 1979 to the '110 application filing date of August 4, 1980. We therefore hold as a matter of law that Hybritech's conception, which was before LJCRF conceived the claimed invention, coupled by diligence to its constructive reduction to practice by the filing of the '110 application, entitle Hybritech to priority over LJCRF. *See* 35 USC 102(g). The work of LJCRF is therefore not prior art.

We also note that there is inadequate factual basis for the district court's holding that LJCRF reduced the claimed invention to practice as early as November 1979 because the only evidence that corroborates the testimony of Ruoslahti, Uotila, and Engvall is the note from Ruoslahti to Uotila, see section A, 2, supra, which indisputably is not

he claimed invention, and the *one* curve from *one* graph from only one page, 43D, of the six Uotila notebooks. After a easoned examination, analysis, and evaluation of this pertinent evidence we conclude that it falls far short of showing he "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as t is hereafter to be applied in practice," *see Coleman,* 754 F.2d at 359, 224 USPQ at 862, and therefore is legally nadequate to support even a holding of *conception* of the claimed invention by LJCRF personnel in 1979.

1) It is undisputed that page 43D was not signed, witnesed, or dated; (2) the deposition testimony of Uotila was that he could not remember the procedure used to arrive at the dose-response curve on page 43D and there was not enough nformation in her notebook to refresh her memory; (3) the testimony of

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Ruoslahti was that he could find *no* data in the notebook supporting that graph, none of the *later* graphs shown there epresented successful assays and that "especially after this was done, we ran into more severe problems. And it took us i while to do away with the problems;" (4) Ruoslahti also testified that they never determined, in 1979, the affinities of he monoclonal antibodies they used, and that the title of page 43D had been altered at some point -- the word inhibition" had been crossed out and "sandwich" written in; and (5) the testimony of Engvall was that there was iothing about the shape of those curves which indicates that they were sandwich assays. We also note, as evidence)earing upon the credibility of Ruoslahti's testimony (that LJCRF actually reduced the claimed invention to practice in 979), that when LJCRF attempted to provoke an interference in the PTO with Hybritech based on the U.S. filing of an ipplication that was the counterpart to a Swedish application disclosing similar subject matter, LJCRF could not lemonstrate even a *prima facie* reduction to practice prior to Hybritech's August 4, 1980, filing date. During that)roceeding, the earliest dates Ruoslahti set down on paper to support conception and reduction to practice were in 980.

2. *The Work of Oi/Herzenberg Is Not the Claimed Invention*

2] It is axiomatic that for prior art to anticipate under §102 it has to meet every element of the claimed invention, and hat such a determination is one of fact. *See, e.g., Lindemann,* supra, 730 F.2d at 1458, 221 USPQ at 485; *Great Northern Corp. v. Davis Core & Pad Co.,* 782 F.2d 159, 165, 228 USPQ 356, 358 (Fed. Cir. 1986). Section 102(g) ipon which the district court relied is one type of "anticipation," i.e., prior invention by another of the same invention. Drs. Oi and Herzenberg testified that their work did not involve detecting the presence of or quantitating antigen but a letermination of the number and location of epitopes on a *known* quantity of antigen. Although this work did involve a sandwich assay to the extent that an antigen was sandwiched between two monoclonal antibodies, it is clear that the similarity between that work and the claimed invention goes no further. Furthermore, both doctors testified that they lid not know the affinities of the antibodies that were used in their mapping work and in fact never calculated them. Ciotti, Monoclonal's expert, testified that the 10 ^{8}affinity limitation cannot be found anywhere in the Oi/Herzenberg work. Again we are left with a definite and firm conviction that a mistake was made because that work does not meet every element of the claimed invention. The district court's finding to the contrary is clearly erroneous.

We note that the district court, in also holding the patent invalid under §103, next considered, combined the Oi/Herzenberg work with the Frankel reference, one justifiable inference therefrom being that the court recognized that Frankel discloses a claim *element* that Oi/Herzenberg does not, namely, at least about 10 ^{8}liters/mole affinity.

IV. *Obviousness, 35 USC 103*

A section 103 obviousness determination -- whether the claimed invention *would have been* (not "would be" as the court repeatedly stated because Monoclonal's pretrial papers used that improper language) obvious at the time the nvention was made is reviewed free of the clearly erroneous standard although the underlying factual inquiries -- scope and content of the prior art, level of ordinary skill in the art, 3 and differences between the prior art and the claimed nvention -- integral parts of the subjective determination involved in §103, are reviewed under that standard. Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered *before* a conclusion on obviousness is reached and is not merely "icing on the cake," as the district court stated at trial. *See Lindemann,* supra, 730 F.2d at 1461, 221 USPQ at 488; *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Kansas Jack, Inc. v. Kuhn,* 719 F.2d 1144, 219 USPQ 856 (Fed. Cir. 1983);

W.L. Gore & Associates v. Garlock Inc., 721 F.2d 1540, 220 USPQ 303, 314 (Fed. Cir. 1983).

1. *The Eight Articles "Predicting" Widespread Use of Monoclonal Antibodies*

Before discussing the more pertinent references in this case -- the Oi/Herzenberg and Frankel works -- we cull the other prior art references relied on by the trial court.

3] First, the latest four of the eight articles that the court stated were of the "utmost importance" because they 'predicted" that the breakthrough in production of monoclonal antibodies by Kohler and Milstein would lead to widespread use of monoclonal antibodies in

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immunoassays are neither 102(a)/103 nor 102(b)/103 prior art because they are dated between late 1979 and March 6, 1980, well after the date of conception and within one year of the filing date of the '110 patent.

The earliest four of the eight articles, on the other hand, although clearly prior art, discuss *production* of monoclonal antibodies -- admittedly old after Kohler and Milstein showed how to produce them -- but none discloses sandwich assays. At *most,* these articles are invitations to try monoclonal antibodies in immunoassays but do not suggest how that end might be accomplished. To the extent the district court relied upon these references to establish that it would have been *obvious to try* monoclonal antibodies of 10 ^{8}liters/mole affinity in a sandwich immunoassay that detects the presence of or quantitates antigen, the court was in error. *See Jones v. Hardy,* 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed. Cir. 1984) ("Obvious to try" is improper consideration in adjudicating obviousness issue). 4

2. *The Kohler and Milstein Work, the Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

The district court's finding that Kohler and Milstein developed a method for producing monoclonal antibodies in vitro is correct, but that finding proves no more; although it made possible all later work in that it paved the way for a supply of monoclonal antibodies, it indisputably does not suggest using monoclonal antibodies in a sandwich assay in accordance with the invention claimed in the '110 patent.

The Cuello reference discloses monoclonal antibodies but not in a sandwich assay. The competitive assay in Cuello, moreover, uses only one monoclonal antibody and thus in no way suggests the claimed invention wherein a ternary complex of two monoclonal antibodies and an antigen form a sandwich. Furthermore, the court did not explain how this art, by itself or in combination with any of the other art, suggests the claimed subject matter and thus why that combination would have been obvious. We are of the opinion that it does not.

The district court correctly found that the use of polyclonal antibodies in sandwich assays was well known. The Jeong patent discloses the use of polyclonal antibodies in a simultaneous sandwich assay, with no suggestion that monoclonal antibodies be so used. It is prior art by virtue of §102(e), application for the patent having been filed September 5, 1978, its effective date as a reference. The Piasio patent, disclosing a reverse sandwich assay using polyclonal antibodies, and Schurrs, disclosing a forward sandwich assay using the same, both §102(a) prior art, are likewise devoid of any suggestion that monoclonal antibodies can be used in a similar fashion.

3. *The Oi/Herzenberg Work and the Frankel Article*

Clearly, the most pertinent items of prior art not cited by the examiner are the Oi/Herzenberg work, as described in section A, 3, supra, and the Frankel article. As stated in the discussion of Prior Invention of Another (section III, 2, supra), the Oi/Herzenberg work involved mapping epitopes on a known quantity of antigen. It was not concerned with and does not disclose using monoclonal antibodies of at least 10 ^{8}liters/mole affinity. Oi and Herzenberg testified that they did not know the affinity of the antibodies used, and Ciotti testified that nowhere in that work is there mention of monoclonal antibody affinity of at least 10 ^{8}liters/mole. On this basis, we conclude that the Oi/Herzenberg work is qualitatively different than the claimed invention; the former is directed to mapping epitopes on a known quantity of antigen and the latter to determining the "presence or concentration of an antigenic substance in a sample of fluid . . . . " We disagree with Monoclonal that these are "essentially the same thing." Furthermore, it is perfectly clear that this

work in no way suggests using monoclonal antibodies of the affinity claimed in the '110 patent. It is because of these differences between the Oi/Herzenberg work and the claimed invention that the fact that an antigen was sandwiched between two monoclonal antibodies in the course of Oi's and Herzenberg's work is not sufficient basis to conclude that the claimed invention would have been obvious at the time it was made to a person of ordinary skill in the art.

Likewise, a conclusion that the invention would have been obvious cannot properly be reached when the Oi/Herzenberg work is

considered in view of the Frankel article. Frankel teaches a method for rapid determination of affinity constants for monoclonal antibodies, some of which clearly have affinities of the order defined by the claims, but does not in any way suggest using two of those antibodies in a sandwich to assay an antigen by forming a ternary complex of labelled antibody, the antigenic substance, and a bound antibody wherein the presence of the antigenic substance is determined by measuring either the amount of labelled antibody bound to a solid carrier or the amount of unreacted labelled antibody. The mere existence of prior art disclosing how to measure the affinity of high affinity monoclonal antibodies is insufficient to support a holding of obviousness. Hybritech's claims define a *process* that *employs* monoclonal antibodies, and does not merely claim antibodies of high affinity. In view of the fact that the Oi/Herzenberg work is not directed to an assay as claimed and does not disclose antibodies of at least 10^8 liters/mole affinity, and further that Frankel fails to suggest using such antibodies in a sandwich assay, the Frankel article does not compensate for the substantial difference between the Oi/Herzenberg work and the claimed subject matter, and therefore those references in combination cannot support a holding of obviousness.

1. *Objective Evidence of Nonobviousness*

[4] In one part of its opinion the court found that "the commercial success of the kits *may* well be attributed to the business expertise and acumen of the plaintiff's personnel, together with its capital base and marketing abilities" (emphasis ours) and later that "[w]here commercial success is based on the sudden availability of starting materials, in this instance the availability of monoclonal antibodies as a result of the Kohler and Milstein discovery, business acumen, marketing ability, and capital sources, no causal relationship is proven." (Citation omitted.)

i. *Commercial Success: Hybritech's Diagnostic Kits Grabbed a Substantial Market Share*

The undisputed evidence is that Hybritech's diagnostic kits had a substantial market impact. The first diagnostic kit sales occurring in mid-1981, sales increased seven million dollars in just over one year, from $6.9 million in-1983 to an estimated $14.5 million in 1984; sales in 1980 were nonexistent. Competing with products from industry giants such as Abbott Labs, Hoffman LaRoche, Becton-Dickinson, and Baxter-Travenol, Hybritech's HCG kit became the market leader with roughly twenty-five percent of the market at the expense of market shares of the other companies. Its PAP kit ranks second only to a product sold by Dupont's New England Nuclear, surpassing products from Baxter-Travenol, Abbott, and others. Hybritech's other kits, indisputably embodying the invention claimed in the '110 patent, obtained similar substantial market positions.

Although the district court did not provide its insights into why commercial success was due to business acumen and not to the merits of the claimed invention, Monoclonal urges in support that it was due to Hybritech's spending disproportionate sums on marketing, 25-30% of income. The undisputed evidence was that expenditures of *mature* companies in this field are between 17 and 32%. Furthermore, the record shows that advertising makes those in the industry -- hospitals, doctors, and clinical laboratories -- aware of the diagnostic kits but does not make these potential users buy them; the products have to work, and there is no evidence that that is not the case here or that the success was not due to the merits of the claimed sandwich assays -- clearly contrary to the district court's finding.

The trial court's finding that the "sudden availability of monoclonals" was the reason for the commercial success of Hybritech's diagnostic kits (Finding 11) is unsupported by the record and clearly erroneous. Monoclonal admits that monoclonal antibodies were available in the United States in *1978*, and the evidence clearly reflects that. Thus, at least *three years* passed between the time monoclonal antibodies were available in adequate supply and the time Hybritech began selling its kits. Especially in the fast-moving biotechnology field, as the evidence shows, that is anything but

udden availability.

ii. *Unexpected Advantages*

Hybritech points to the testimony of three witnesses skilled in the diagnostic field who state that, based on tests done in heir laboratories as a result of real-world comparisons in the normal course of research, the diagnostic kits that embody he '110 invention unexpectedly solved longstanding problems. Dr. Hussa, the head of a large referral laboratory and a vorld-wide consultant, testified that until Hybritech introduced its kits, he and others were very skeptical and had lmost exclusively used competitive assays with a radioactive tracer (RIAs). 5 In relation to an HCG Hybritech

:it, he testified that he had first thought that the Hybritech HCG kit would not give accurate results for low antigen :oncentrations because that condition is indicated in the Hybritech kit by a low radioactivity reading, a reading difficult o differentiate from control samples containing no antigen. He also stated that in the past, RIA kits falsely detected HCG in nonpregnant women, a condition which would indicate cancer and surgery. He stated that when he employed he Hybritech HCG kit in such instances it demonstrated, correctly and absent any difficulty interpreting the data, that lo HCG was present.

Dr. Blethen, an M.D. holding a Ph.D. in biochemistry, testified that she did not think that the Hybritech HGH kit, for letecting growth hormone in children, would offer any advantage, but she determined that it detected HGH deficiencies n children where conventional RIAs failed to do so. She also stated that the kit does not give false positive readings as lo conventional RIA kits, an opinion shared by Dr. Hussa. A third witness, Dr. Herschman, who holds a master's legree in chemistry, testified that he spent years working on the development of an assay that would determine the presence of TSH (thyroid stimulating hormone) with greater sensitivity. He succeeded but discovered that the Hybritech TSH kit had the same sensitivity, the test being performed in four hours rather than the three days his kit equired.

Having considered the evidence of nonobviousness required by §103 and *Graham,* supra, we hold, as a matter of law, hat the claimed subject matter of the '110 patent would not have been obvious to one of ordinary skill in the art at the ime the invention was made and therefore reverse the court's judgment to the contrary. The large number of eferences, as a whole, relied upon by the district court to show obviousness, about twenty in number, skirt all around but do not as a whole suggest the claimed invention, which they must, to overcome the presumed validity, *Lindemann,* 730 F.2d at 1462, 221 USPQ at 488, *as a whole. See* 35 USC 103; *Jones v. Hardy,* 727 F.2d 1524, 1529, 220 USPQ 1021, 1024 (Fed. Cir. 1984). Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, as the district court did in frequently describing the claimed invention as the mere substitution of nonoclonal for polyclonal antibodies in a sandwich assay, was a legally improper way to simplify the difficult letermination of obviousness. *See generally Hodosh v. Block Drug Co,* 786 F.2d 1136, 229 USPQ 182 (Fed. Cir. 1986). 6

With respect to the objective indicia of nonobviousness, while there is evidence that marketing and financing played a ole in the success of Hybritech's kits, as they do with any product, it is clear to us on the entire record that the commercial success here was due to the merits of the claimed invention. It cannot be argued on this record that Hybritech's success would have been as great and as prolonged as admittedly it has been if that success were not due to he merits of the invention. The evidence is that these kits compete successfully with numerous others for the trust of persons who have to make fast, accurate, and safe diagnoses. This is not the kind of merchandise that can be sold by advertising hyperbole.

V. *Enablement, Best Mode, and Definiteness Under §112*

The section 112 defense appears to have been an afterthought of both Monoclonal, who briefly but unsuccessfully attempts to defend this utterly baseless determination, and of the district court which adopted the defense from Monoclonal's pretrial papers apparently without knowledge of the applicable law, to highlight, as it stated at trial, that it was part of its job to see that "whoever wins wins all the way or whoever loses loses all the way." Taken as a whole, he court's comments on §112 -- split into two parts, one from Monoclonal's pretrial brief and the other from the

idopted pretrial

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indings and conclusions -- are internally inconsistent. The opinion states that the patent fails to disclose how (1) to nake monoclonal antibodies; (2) to screen for proper monoclonal antibodies; and (3) to measure monoclonal antibody iffinity and therefore the specification is nonenabling and does not satisfy the best mode requirement, and the claims ire indefinite. We discuss each of these in turn.

1. *Enablement*

Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed nvention, *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 USPQ 592, 599 (Fed. Cir. 1983), is not precluded :ven if some experimentation is necessary, although the amount of experimentation needed must not be unduly :xtensive, *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), and is determined as of the filing date of the patent application, which was August 4, 1980. *See W.L. Gore and Associates v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983). Furthermore, a patent need not each, and preferably omits, what is well known in the art. *Lindemann*, 730 F.2d at 1463, 221 USPQ at 489.

The record fully supports the '110 patent's statement that

The monoclonal antibodies used for the present invention are obtained by the [hybridoma] process discussed by Milstein and Kohler. . . . The details of this process are well known and not repeated here.

The district court itself stated that the "method for producing monoclonal antibodies in vitro was well known prior to he alleged invention of the '110 patent," and used the "sudden availability of monoclonal antibodies" produced by the Kohler and Milstein discovery to support, albeit erroneously, its finding of a lack of nexus between the merits of the :laimed invention and its commercial success. The court then about-faced and held the '110 patent deficient because it 'ails to teach how to make monoclonal antibodies.

With respect to screening, the only permissible view of the evidence is that screening methods used to identify the necessary characteristics, including affinity, of the monoclonal antibodies used in the invention were known in the art and that the '110 patent contemplated one of those. At trial, Monoclonal's counsel stated "it is a procedure that was known in '78." In similar fashion, the district court held that the claimed subject matter would have been obvious in part because the "existence of monoclonal antibodies *having the affinity constants claimed in the patent was well known* prior to the alleged invention . . . ." [Emphasis ours.] Furthermore, there was not a shred of evidence that undue experimentation was required by those skilled in the art to practice the invention. We hold as a matter of law that the 110 patent disclosure is enabling.

2. *Best Mode*

'The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 USC 112. Because not complying with the best mode requirement amounts to concealing the preferred mode contemplated by the applicant at the time of filing, in order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed. *DeGeorge v. Bernier*, 768 F.2d 1318, 1324, 226 USPQ 758, 763 (Fed. Cir. 1985) (quoting with approval *In re Sherwood*, 613 F.2d 809, 204 USPQ 537 (CCPA 1980)). The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening and that the screening process is labor-intensive and time-consuming. It is not plausible that this evidence amounts to proof of concealment of a best mode for screening or producing monoclonal antibodies for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's finding that the best mode requirement was not satisfied is clearly erroneous.

3. *Indefiniteness*

[5] The basis of the district court's holding that the claims are indefinite is that "they do not disclose how infringement may be avoided because antibody affinity cannot be estimated with any consistency." (Conclusion 6.) Even if the

listrict court's finding in support of this holding -- that "there is no standard set of experimental conditions which are used to estimate affinities" -- is accurate, under the law pertaining to indefiniteness -- "if the claims, read in light of the pecification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the anguage is as precise as the subject matter permits, the courts can demand no more," *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) -- the claims clearly are definite. The evidence of record indisputably shows that calculating affinity was known in the art at the time of filing, and

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notwithstanding the fact that those calculations are not precise, or "standard," the claims, read in light of the pecification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of aw, no court can demand more.

VI. *Motions*

Monoclonal's motion to strike Appendices A and B of Hybritech's reply brief as being beyond the page limit applicable o reply briefs is granted as to Appendix A but denied as to Appendix B, the latter having been helpful in culling the often non-supportive citations to the record by Monoclonal.

Hybritech's motion to supplement the record with a Monoclonal advertisement not considered at trial is denied. Any adverse impact that the disposition of these two motions has upon either party is more than outweighed by this court's patience with the seemingly endless flow of post-argument argumentative papers.

VII. *Conclusion*

The judgment of the district court holding the patent in suit invalid is *reversed* in all respects, and the case is *remanded* for a determination of the issue of infringement which the court held was moot.

REVERSED AND REMANDED

Footnotes

Footnote 1. With respect to obviousness, one portion of the district court's opinion apparently relies on all of the above listed references, (1)-(5), for the obviousness holding while a later portion entitled "CONCLUSIONS OF LAW" relies on only the Oi/Herzenberg and Frankel articles. Furthermore, the district court did not state that the LJCRF work was considered for purposes of §103, although we recognize that §102(g) prior art can be used for §103.

Footnote 2. A dose response curve is antigen concentration plotted against the signal produced by labelled antibody in an immunoassay. The signal increases with increasing antigen concentration in a successful assay but at some point decreases when the antigen concentration becomes too high.

Footnote 3. Although the district court failed expressly to find the level of ordinary skill in the art at the time the invention was made, it did make reference to "[p]eople working in immunology aware of the Kohler and Milstein discovery" which we deem an accurate finding for the purposes of that portion of the *Graham* factual inquiries.

Footnote 4. Finding 10, which states that the invention was contemporaneously developed and disclosed in at least five publications and patent applications not listed above *and dated well after the filing date of the '110 patent but before its issuance* is irrelevant for purposes of the hypothesis based on the three factual inquiries required by §103 as interpreted by *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966) because obviousness must be determined as of the time the invention was made. Additionally, they are of little probative value in this case because they are dated December 1981 at the earliest, more than a year after the August 4, 1980, filing date here and roughly two years after conception occurred. Furthermore, simultaneous development may or may not be indicative of obviousness, the latter being the case here for the above reasons and because the other evidence of nonobviousness is adequate, such occurrences having

)een provided for in 35 USC 135. *Linaemann,* supra, 730 F.2d at 1460-61, 221 USPQ at 487; *Environmental Designs, Ltd. v. Union Oil Co. of California,* 713 F.2d 693, 698 n.7, 218 USPQ 865 , 869 n.7 (Fed. Cir. 1983)

Footnote 5. Monoclonal's expert Blakemore testified that of 425 assays on the market in 1979 less than 1% were sandwich assays. Today, sandwich assays constitute the majority of all assays sold.

The record also shows that Blakemore, who testified extensively for Monoclonal that the claimed invention would have)een obvious, never used monoclonal antibodies in sandwich assays at Cetus before 1980. Additionally, she did not :ven mention them in the Jeong patent, of which she was a coinventor, which issued January 13, 1981, long after the)eginning of Hybritech's work in this area in 1979.

Footnote 6. It bears repeating that it is crucial that counsel set forth the law accurately. More particularly, it is the duty)f counsel to impart to the judge that the obviousness question properly is whether the *claimed* invention *as a whole vould have been* obvious to one of *ordinary* skill in the art *at the time the invention was made,* and that the district :ourt must *expressly* make the three factual determinations required by *Graham* and consider objective evidence of)bviousness *before* the legal conclusion of obviousness vel non is made. Submitting to the court language like "any lifferences . . . would have been obvious," as was done here, violates the axiom that the question is not whether the lifferences would have been obvious but the claimed invention *as a whole.* Furthermore, arguing that "it would be)bvious" rather than that it would *have been* obvious shifts the court's focus to the wrong period of time, namely to a ime long after the invention was made, in which, more likely than not, the prior art and the level of ordinary skill in the irt are more advanced. *See* 35 USC 103.

- End of Case -

Print-Friendly Version

In re HOEKSEMA, 158 USPQ 596 (CCPA 1968)

In re HOEKSEMA

(CCPA)
158 USPQ 596

Decided Aug. 8, 1968
No. 7778
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Rehearing and reopening—In general (§ 57.1)

Court of Customs and Patent Appeals grants rehearing because of continuing importance of questions involved and strong suggestion of error in its earlier opinion.—In re Hoeksema (CCPA) 158 USPQ 596.

2. Patentability—Composition of matter (§ 51.30)

Process obviousness is relevant in deciding compound obviousness.—In re Hoeksema (CCPA) 158 USPQ

3. Patentability—Invention—In general (§ 51.501)

In context of 35 U.S.C. 103, court is not permitted to fragment a claimed invention in applying that section; invention must be considered as a whole.—In re Hoeksema (CCPA) 158 USPQ 596.

4. Patentability — Composition of matter (§ 51.30)

Claimed compound is the invention as a whole (35 U.S.C. 103), but, so considered, unless there is some known or obvious way to make compound, invention is nothing more than a mental concept expressed in chemical terms and formulae on a paper; invention as a whole is claimed compound and a way to produce it; since there is no showing that claimed compound can exist because there is no showing of a known or obvious way to manufacture it, the invention as a whole is not obvious under section 103.—In re Hoeksema (CCPA) 158 USPQ 596.

5. Patentability — Anticipation — In general (§ 51.201)

Patentability — Invention—In general (§ 51.501)

Conditions for patentability, novelty and loss of right to patent, stated in 35 U.S.C. 102, may have relevance as to disclosure which must be found in prior art to find obviousness of invention under section 103; in determining that quantum of prior art disclosure which is necessary to declare applicant's invention "not novel" or "anticipated" within section 102, test is whether reference contains an enabling disclosure; this test applies to issues under section 103.—In re Hoeksema (CCPA) 158 USPQ 596.

6. Patentability—Composition of matter (§ 51.30)

If prior art fails to disclose or render obvious a method for making claimed compound, at time invention was made, it may not be legally concluded that compound itself is in possession of public; absence of known or obvious process for making claimed compounds overcomes presumption that compounds are obvious, based on close relationships between their structures and those of prior art compounds.—In re Hoeksema (CCPA) 158 USPQ 596.

7. Pleading and practice in Patent Office—Rejections (§ 54.7)

Patent Office having cited reference which rendered claimed compounds prima facie obvious, applicant sustained burden of going forward with contrary evidence by filing affidavit pointing out that reference does not disclose process for producing claimed compounds, thus overcoming Office's position as to reference's legal effect under 35 U.S.C. 103; thereupon, burden of going forward with proofs to support its position as to obviousness shifted to Office; Office's failure to produce such evidence requires that rejection be reversed.—In re Hoeksema (CCPA) 158 USPQ 596.

Particular patents — 9-D-Psicofuranosylpurine

Hoeksema, 9-D-Psicofuranosylpurine and 6-Substituted Derivatives, claim 1 of application allowed.—In re Hoeksema CCPA) 158 USPQ 596.

Case History and Disposition:

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Appeal from Board of Appeals of the Patent Office.

Application for patent of Herman Hoeksema, Serial No. 30,770, filed May 23, 1960; Patent Office Group 120. From decision rejecting claim 1, applicant appeals. Affirmed at 154 USPQ 169. On petition for rehearing. Reversed; Kirkpatrick, Judge, dissenting with opinion.

Attorneys:

EARL C. SPAETH (EUGENE O. RETTER and GEORGE T. JOHANNESEN of counsel) all of Kalamazoo, Mich., for appellant.

JOSEPH SCHIMMEL (JACK E. ARMORE of counsel) for Commissioner of Patents.

Judge:

Before WORLEY, Chief Judge, RICH, SMITH, and ALMOND, Associate Judges, and KIRKPATRICK, Judge.

Opinion Text

Opinion By:
SMITH, Judge.

1] In our prior consideration of this appeal, we affirmed the decision of the Patent Office Board of Appeals, which had affirmed the examiner's rejection of the sole remaining claim of appellant's application, [1]In re Hoeksema, 54 CCPA 618, 379 F.2d 1007, 154 USPQ 169 (1967). Because of the continuing importance of the questions involved, and the strong suggestion of error in our earlier opinion, we granted appellant's petition for a rehearing under the provisions of Rule 7 of this court, 55 CCPA—, (October 5, 1967).

The parties filed new briefs, and the case was reargued on January 3, 1968. Upon reconsideration of our previous decision, we have concluded that our previous decision was erroneous and that a proper resolution of the issues requires that we *reverse* the decision of the board.

The facts are set forth in our original opinion. We shall assume familiarity with that statement of facts and shall here redevelop only those which we now believe were previously misapprehended or misapplied and require the present decision.

The sole claim on appeal is directed to a chemical compound and reads as

1. An N-psicofuranoside having the formula:

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Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

wherein A is selected from the class consisting of hydrogen, the group -XR wherein R is selected from the class consisting of hydrogen, lower-alkyl, and lower-aralkyl, and X is selected from the class consisting of oxygen and sulfur, and the group
Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.
wherein R_2 is selected from the class consisting of hydrogen, lower-alkyl, lower-aralkyl, and lower-aryl, and R_3 is selected from the class consisting of lower-alkyl, lower-aralkyl, and lower-aryl, and R¢ is selected from the class consisting of hydrogen, a hydrocarbon carboxylic acid acyl radical containing from two to twelve carbon atoms, inclusive, and a halo-, hydroxy-, lower-alkoxy-, amino-, cyano-, thiocyano-, and nitro-substituted hydrocarbon carboxylic acid acyl radical containing from two to twelve carbon atoms, inclusive.

That claim stands rejected under 35 U.S.C. 103 as unpatentable over prior art, on this record limited solely to the De Boer et al. patent [2](De Boer) which discloses a compound with the structural formula:
Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

As we noted in our original opinion, the controversy here is limited to the substituent A at the 6-position of the purine ring system. Although a compound having De Boer's structure is not included in the appealed claim since A in the claim cannot be an unsubstituted or primary amino,
Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.
the basic structure of the De Boer compound is similar to the structure of appellant's alkylamino and dialkylamino compounds. [3]

Despite this close structural similarity between the De Boer amino compound and the alkylamino and dialkylamino

ompounds included in the appealed claim, appellant chose not to submit a showing of unexpected properties in his laimed compounds. [4] Appellant asserted that his compounds were unobvious and patentable without such a showing. He urged that De Boer does not teach one of ordinary skill in the art how to make appellant's claimed compounds, and he examiner did not cite any other reference telling how they might be made. Therefore, in appellant's view, his laimed compounds are not in possession of the public, In re Brown, 51 CCPA 1254, 329 F.2d 1066, 141 USPQ 245 1964). [5]

n support of his position, appellant submitted an affidavit by Dr. Paul F. Wiley relating to the unavailability to the ublic of processes for preparing appellant's alkylamino and dialkylamino compounds. [6] Dr. Wiley's qualifications

nd competence as an expert to state facts and opinion in this area of chemistry were not challenged.

Regarding the Wiley affidavit, the examiner stated, in his Answer:

> The affidavit * * * does not appear to be pertinent to the claim now on appeal because it is directed to the processes by which the De Boer et al. and appellant's compounds are prepared, and shows nothing unobvious for the instantly claimed compound.

Concerning the Wiley affidavit, the board cited a statement of this court in In re Riden, 50 CCPA 1411, 318 F.2d 761, 38 USPQ 112 (1963), to the effect that "the method of making the compounds is a relevant fact to be considered in the uestion of obviousness of the compounds," 50 CCPA at 1415, 318 F.2d at 764, 138 USPQ at 114-115. But the board ontinued:

> * * * This may be so but it is only one factor and, in our opinion, should never be the overriding one which appellant is here, in effect, urging.

Appellant states the first of two central questions to be decided in this rehearing as follows:

> 1) Appellant will admit his compounds are obvious and unpatentable *if* an obvious process is available to make them. Does it follow then that appellant's compounds are unobvious and patentable if an obvious process is *not* available to make them?

2] Within this context, appellant simplifies that question to: Is process obviousness relevant in deciding compound bviousness? [7]

The solicitor responds to the latter characterization of the question in the affirmative, pointing out that the first question ears on the principle implicit in In re Brown, supra, that claimed compounds not distinguished in their properties over losely related prior art compounds are unpatentable thereover where the claimed compounds would be "in possession f the public" in that a process for preparing them would be obvious to those of ordinary skill in the art.

n addition, the solicitor now refers to our prior opinion in which we noted that the facts in this case are closely nalogous to those of In re Riden, supra, where we stated that the fact that the method of making the claimed ompound is relevant, 54 CCPA at—, 379 F.2d at 1010, 154 USPQ at 172.

A recurring problem of analysis which confronted us as we prepared our previous opinion, and which still confronts us fter the rehearing, has its genesis in a proper understanding of the issue as framed by appellant. In effect, appellant grees that since the claimed product is a homolog of a known compound, it would be prima facie "obvious" under 35 J.S.C. 103. But this agreement is conditioned on the proviso that there is in the prior art an "obvious" process by which o make that compound.

3] In the context of section 103, we are not permitted to fragment a claimed invention in applying that section. The lear mandate of the statute which governs our analysis requires that

ve consider the *invention as a whole* in making the determination.

4] Thus, as we apply the statute to the present invention, we must ask first, what is the invention as a whole? Necessarily, by elementary patent law principles, it is the claimed compound, but, so considered, unless there is some nown or obvious way to make the compound, the invention is nothing more than a mental concept expressed in hemical terms and formulae on a paper.

Ve are certain, however, that the invention as a whole is the claimed compound *and* a way to produce it, wherefore ppellant's argument has substance. There has been no showing by the Patent Office in this record that the claimed ompound can exist because there is no showing of a known or obvious way to manufacture it; hence, it seems to us hat the "invention as a whole," which section 103 demands that we consider, is not obvious from the prior art of ecord.

While there are valid reasons based in public policy as to why this defect in the prior art precludes a finding of bviousness under section 103, In re Brown, supra, its immediate significance in the present inquiry is that it poses yet *nother difference* between the claimed invention and the prior art which *must* be considered in the context of section 03. So considered, we think the differences between appellant's *invention as a whole* and the prior art are such that the laimed invention would not be obvious within the contemplation of 35 U.S.C. 103.

5] While 35 U.S.C. 102 is not *directly* involved in the issue on review, the conditions for patentability, novelty and oss of right to patent, there stated, may have relevance as to the disclosure which must be found in the prior art to find bviousness of an invention under section 103. In determining that quantum of prior art disclosure which is necessary o declare an applicant's invention "not novel" or "anticipated" within section 102, the stated test is whether a reference ontains an "enabling disclosure," in the present context, a process by which the claimed compound could be made. In n re LeGrice, 49 CCPA 1124, 301 F.2d 929, 133 USPQ 365 (1962), we observed that the resolution of this issue equired us to determine whether, *as a matter of law,* a reference without such a disclosure constituted a statutory time ar to an applicant's right to a patent. There, the issue was founded on 35 U.S.C. 102(b), not 103, but our conclusions ave a certain pertinence here. We concluded, id. at 1134, 301 F.2d at 936, 133 USPQ at 372:

> We think it is sound law, consistent with the public policy underlying our patent law, that before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in *combination with his own knowledge of the particular art and be in possession of the invention.* * * *

n In re Brown, supra, this court discussed In re Von Bramer, 29 CCPA 1018, 127 F.2d 149, 53 USPQ 345 (1942), ommenting that that opinion should not be construed to encompass what had come to be called the "Von Bramer loctrine." There we stated, 51 CCPA at 1257, 329 F.2d at 1009, 141 USPQ at 247:

> * * * This doctrine, which appears to have resulted from In re Von Bramer et al., supra, seems over a period of years to have been tailored in some quarters to a principle which defeats the novelty of a chemical compound on the basis of a mere printed conception or a mere printed contemplation of a chemical "compound" *irrespective of the fact* that so-called "compound" *described in the reference is not in existence or that there is no process shown in the reference for preparing the compound, or that there is no process known to a person having ordinary skill in the relevant art for preparing the compound.* In other words, a mere formula or a mere sequence of letters which constitute the designation of a "compound," is considered adequate to show that a compound in an application before the Patent Office, which compound is designated by the same formula or the same sequence of letters, is old. We do not think that the Von Bramer case should be so construed. [Emphasis added.]
>
> To the extent that anyone may draw an inference from the Von Bramer case that the *mere* printed conception or the *mere* printed contemplation which constitutes the designation of a "compound" is sufficient to show that such a compound is old, regardless of whether the compound is involved in a 35 U.S.C. 102 or 35 U.S.C. 103 rejection, we totally disagree. * * * [Footnotes omitted.]

Ve concluded, relying on In re Le Grice, supra, and E. I. du Pont de Nemours & Co. v. Ladd, 328 F.2d 547, 140 USPQ 97 (D.C. Cir. 1964), that the "true test of any prior art relied on to show or suggest that a chemical compound is old, is /hether the prior

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rt is such as to place the disclosed 'compound' in the *possession of the public.* " 51 CCPA at 1259, 329 F.2d at 1011, 41 USPQ at 249.

While In re Le Grice was bottomed on an issue arising under 35 U.S.C. 102 where the reference was a "printed ublication," that test, in our view, is also properly applicable to issues arising under 35 U.S.C. 103. See In re Brown, upra (pertinent portion quoted above); Deutsche Gold-Und Silber-Scheideanstalt v. Commissioner, 251 F.Supp. 624, 29-630, 148 USPQ 412, 416 (D.D.C. 1966), affirmed, __F.2d__, 157 USPQ 549 (D.C. Cir. 1968).

6] Thus, upon careful reconsideration it is our view that if the prior art of record fails to disclose or render obvious a nethod for making a claimed compound, at the time the invention was made, it may not be legally concluded that the ompound itself is in the possession of the public. [8]In this context, we say that the absence of a known or obvious rocess for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close elationships between their structures and those of prior art compounds.

The second aspect of the questions presented by this rehearing involves the issue of whether the burden is on the Patent Office to provide the evidence on which to predicate process obviousness.

35 U.S.C. 101 states, in its preamble, that an applicant is *entitled* to a patent *unless* certain patent-defeating provisions are met. The substantive patent-defeating provisions are encompassed in 35 U.S.C. 100-103.

7] As we have stated, the Patent Office search resulted in citation of the De Boer reference which, under the prevailing law, rendered appellant's claimed compounds prima facie obvious. In other words, its citation shifted to appellant the burden of going forward with contrary evidence. Appellant filed the affidavit of Dr. Wiley which points out as a fact that De Boer—the only reference being relied on—does not disclose a process for producing the different compounds here claimed.

We think that portion of the Wiley affidavit set forth, supra note 6, states facts which were legally sufficient to overcome the position of the Patent Office as to the legal effect under section 103 of the De Boer reference. [9] Appellant's responsibility to overcome this reference as a "patent-defeating" reference under section 103 at that point in the prosecution was only to overcome De Boer as a reference pertinent to the issue of obviousness under section 103.

We think the Wiley affidavit is clearly sufficient for this purpose. The affidavit points out that there is no indication in the De Boer patent that the fermentation process used to produce De Boer's compounds could be used to produce appellant's compounds. Since we are of the view that the method for making the compounds is an integral part of the "invention as a whole" which we must consider under section 103, we conclude that the burden of going forward with proofs to support its position as to obviousness of the claimed invention shifted to the Patent Office upon appellant's filing of the Wiley affidavit.

The failure of the Patent Office to produce such evidence requires that the decision of the board be *reversed.*

WORLEY, Chief Judge, did not participate.

Footnotes

Footnote 1. Claim 1 in Serial No. 30,770, filed May 23, 1960, for "9-D-Psicofuranosylpurine and 6-Substituted Derivatives." Claims 2 and 11-15 stand allowed.

Footnote 2. Patent No. 3,094,460, issued June 18, 1963 on an application filed January 20, 1959.

ootnote 3. Appellant, in effect, admits that there is such a "structural similarity" between his claimed compounds and the prior art compounds s to raise an "inference of fact" that they are not patentable within the meaning of 35 U.S.C. 103. See In re Papesch, 50 CCPA 1084, 315 F.2d 81, 137 USPQ 43 (1963); In re Victor Mills, 47 CCPA 1185, 281 F.2d 218, 126 USPQ 513 (1960).

ootnote 4. Such a showing often has been treated by this court as overcoming a case of "prima facie obviousness" or the "inference of fact" iat the compounds are obvious. See, e.g., In re Papesch, supra note 3 and cases cited therein.

ootnote 5. For the applicability of In re Brown, supra, to other factual contexts, see In re Bird, 52 CCPA 1290, 1294, 344 F.2d 979, 982, 145 JSPQ 418, 420 (1965); In re Sheppard, 52 CCPA 859, 864, 339 F.2d 238, 242, 144 USPQ 42, 45 (1964); Dix-Seal Corp. v. New Haven Trap :ock Co., 236 F.Supp. 914, 921, 144 USPQ 57, 64 (D.C. Conn. 1964).

ootnote 6. After setting forth his qualifications and stating that he had read and understood both appellant's application and the prior art patent,)r. Wiley stated:

> THAT, 6-amino-9-D-psicofuranosylpurine is a systematic name for "psicofuranine" which is disclosed in column 6, lines 46-62 of the aforesaid patent;
>
> THAT, according to the aforesaid patent, 6-amino-9-D-psicofuranosylpurine is produced by a fermentation process involving the action of a specific micro-organism, S, hygroscopicus var. decoyinine, in certain aqueous nutrient media;
>
> THAT, *there is no indication in the aforesaid patent* [De Boer] *that the aforesaid fermentation process could be used to produce 6-lower-alkylamino-9-D-psicofuranosylpurines, 6-di-lower-alkylamino-9-D-psicofuranosylpurines, or other 6-substituted-amino-9-D-piscofuranosylpurines;*
>
> THAT, he does not believe the aforesaid fermentation process could be adapted to the production of the aforesaid 6-lower-alkylamino-9-D-psicofuranosylpurines, 6-di-lower-alkyamino-9-D - psicofuranosylpurines, or other 6-substituted-amino-9-D-psicofuranosylpurines;
>
> THAT, *the aforesaid 6-amino-9-psicofuranosylpurine could not be transformed by direct chemical substitution of the 6-amino group to a 6-lower-alkylamino-9-D-psicofuranosylpurine,* a 6-di-lower alkylamino-9-D-psicofuranosylpurine, or other 6-substituted-amino-9-D-psicofuranosylpurines, *and that such transformations could be carried out only by a complex multi-step procedure such as that described in the aforesaid patent application Serial No. 30,770.* [Emphasis added.]

Footnote 7. To this extent, appellant has misstated his argument. That process obviousness is relevant in this context is clear from In re Riden, upra. See also In re Chapman, 53 CCPA 978, 357 F.2d 418, 148 USPQ 711 (1966); In re Burt, 53 CCPA 929, 356 F.2d 115, 148 USPQ 548 1966); In re Schechter, 40 CCPA 1009, 205 F.2d 185, 98 USPQ 144 (1963).

We think appellant really means to say that the question is whether a claimed compound may be said to be legally)bvious when no process for making that compound is shown in the prior art relied upon to establish legal obviousness inder section 103.

Footnote 8. In Phillips Petroleum v. Ladd, 219 F.Supp. 366, 138 USPQ 421 (D.D.C. 1963), in considering a rejection arising under 35 U.S.C. 102, the District Court agreed with this court that the mere naked statement of the invention does not put anyone in possession of the invention. That court was careful to note that no process had been shown in the reference for preparing the compound and that no process was known to)ne of ordinary skill in the art for preparing the compound.

In Ex parte Wall, 156 USPQ 95 (P.O. Bd. App. 1964), the board considered a rejection under 35 U.S.C. 102 of a claim reading "Perfluorostyrene." In reversing the examiner, the board commented that the examiner did not contend that the reference disclosed how perfluorostyrene is made, nor did he point to any extraneous evidence which would indicate

hat those skilled in the art knew how to make that compound.

Footnote 9. We think this approach to be eminently fair to all parties and in accord with the opinion of the Supreme Court in Graham, in its equiring that all of the pertinent evidence be considered while yet leaving the primary responsibility for sifting out unpatentable material with he Patent Office, Graham v. John Deere Co., 383 U.S. 1 at 18, 148 USPQ at 467.

t would be practically impossible for an applicant to show that all known processes are incapable of producing the claimed compound.

Dissenting Opinion Text

Dissent By:
KIRKPATRICK, Judge, dissenting.

am unable to agree with the result reached by the majority. The reasons for my dissent appear in the overruled opinion n re Hoeksema, 54 CCPA 1618, 379 F.2d 1007, 154 USPQ 169 (1967).

Footnote * Senior District Judge, Eastern District of Pennsylvania, sitting by

- End of Case -

Print-Friendly Version

As noted in *Brouwer*, 77 F.3d at 425, 37 USPQ2d at 1666, the inquiry as to whether a claimed invention would have been obvious is "highly fact-specific by design". Accordingly, obviousness must be assessed on a case-by-case basis. The following decisions are illustrative of the lack of *per se* rules in applying the test for obviousness under 35 U.S.C. 103 and of the fact-intensive comparison of claimed processes with the prior art: *In re Durden*, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985) (The examiner rejected a claim directed to a process in which patentable starting materials were reacted to form patentable end products. The prior art showed the same chemical reaction mechanism applied to other chemicals. The court held that the process claim was obvious over the prior art.); *In re Albertson*, 332 F.2d 379, 141 USPQ 730 (CCPA 1964) (Process of chemically reducing one novel, nonobvious material to obtain another novel, nonobvious material was claimed. The process was held obvious because the reduction reaction was old.); *In re Kanter*, 399 F.2d 249, 158 USPQ 331 (CCPA 1968) (Process of siliconizing a patentable base material to obtain a patentable product was claimed. Rejection based on prior art teaching the siliconizing process as applied to a different base material was upheld.); Cf. *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990) (Methods of bonding polymer and filler using a novel silane coupling agent held patentable even though methods of bonding using other silane coupling agents were well known because the process could not be conducted without the new agent); *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973) (Process of cracking hydrocarbons using novel zeolite catalyst found to be patentable even though catalytic cracking process was old. "The test under 103 is whether in view of the prior art the invention as a whole would have been obvious at the time it was made, and the prior art here does not include the zeolite, ZK-22. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties." 475 F.2d at 664-665, 177 USPQ at 255.); and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974) (Claim to a process for the production of a known antibiotic by cultivating a novel, unobvious microorganism was found to be patentable.).

2121 Prior Art; General Level of Operability Required to Make a *Prima Facie* Case

PRIOR ART IS PRESUMED TO BE OPERABLE/ ENABLING

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

WHAT CONSTITUTES AN "ENABLING DISCLOSURE" DOES NOT DEPEND ON THE TYPE OF PRIOR ART THE DISCLOSURE IS CONTAINED IN

The level of disclosure required within a reference to make it an "enabling disclosure" is the same no matter what type of prior art is at issue. It does not matter whether the prior art reference is a U.S. patent, foreign patent, a printed publication or other. There is no basis in the statute (35 U.S.C. 102 or 103) for discriminating either in favor of or against prior art references on the basis of nationality. *In re Moreton*, 288 F.2d 708, 129 USPQ 227 (CCPA 1961).

2121.01 Use of Prior Art in Rejections Where Operability Is in Question

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

the *Graham* factual inquiries. It should be noted that the Supreme Court's application of the *Graham* test to the fact circumstances in *Ag Pro* was somewhat stringent, as it was in *Black Rock*. Note *Republic Industries, Inc. v. Schlage Lock Co.*, 592 F.2d 963, 200 USPQ 769 (7th Cir. 1979). The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540, 218 USPQ 871, 880 (Fed. Cir. 1983) that

> A requirement for "synergism" or a "synergistic effect" is nowhere found in the statute, 35 U.S.C. When present, for example in a chemical case, synergism may point toward nonobviousness, but its absence has no place in evaluating the evidence on obviousness. The more objective findings suggested in *Graham*, supra, are drawn from the language of the statute and are fully adequate guides for evaluating the evidence relating to compliance with 35 U.S.C. § 103. *Bowser Inc. v. United States*, 388 F. 2d 346, 156 USPQ 406 (Ct. Cl. 1967).

BASIC CONSIDERATIONS WHICH APPLY TO OBVIOUSNESS REJECTIONS

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

OBJECTIVE EVIDENCE MUST BE CONSIDERED

Objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of any of these secondary considerations is submitted, the examiner must evaluate the evidence. The weight to be accorded to the evidence depends on the individual factual circumstances of each case. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). The ultimate determination on patentability is made on the entire record. *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

See MPEP § 716- § 716.06 for a discussion of objective evidence and its role in the final legal determination of whether a claimed invention would have been obvious under 35 U.S.C. 103.

2141.01 Scope and Content of the Prior Art

I. PRIOR ART AVAILABLE UNDER 35 U.S.C. 102 IS AVAILABLE UNDER 35 U.S.C. 103

"Before answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). Subject matter that is prior art under 35 U.S.C. 102 can be used to support a rejection under section 103. *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. Pat. App. & Inter. 1981) ("it appears to us that the commentator [of 35 U.S.C.A.] and the [congressional] committee viewed section 103 as including all of the various bars to a patent as set forth in section 102.").

A 35 U.S.C. 103 rejection is based on 35 U.S.C. 102(a), 102(b), 102(e), etc. depending on the type of prior art reference used and its publication or issue date. For instance, an obviousness rejection over a U.S. patent which was issued more than 1 year before the filing date of the application is said to be a statutory bar just as if it anticipated the claims under 35 U.S.C. 102(b). Analogously, an obviousness rejection based on a publication which would be applied under 102(a) if it anticipated the claims can be overcome by swearing behind the publication date of the reference by filing an affidavit or declaration under 37 CFR 1.131.

For an overview of what constitutes prior art under 35 U.S.C. 102, see MPEP § 901 - § 901.06(d) and § 2121 - § 2129.

In re WESSLAU, 147 USPQ 391 (CCPA 1965)

In re WESSLAU

(CCPA)
147 USPQ 391

Decided Nov. 26, 1965
Appl. No. 7447
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability--Composition of matter (§ 51.30)

Claims to process of polymerizing ethylene are not rejected on theory that applicant's catalyst system can be met merely by substitution of groups from two prior patents on the corresponding components of a third prior system since no one of the references suggests such a substitution, quite apart from the result which would be obtained thereby; such piecemeal reconstruction of prior art patents in light of applicant's disclosure is contrary to 35 U.S.C. 103.

2. Patentability--Invention--In general (§ 51.501)

Question in cases within ambit of 35 U.S.C. 103 is whether subject matter as a whole would have been obvious to one of ordinary skill in the art following teachings of prior art at time invention was made; it is impermissible within framework of section 103 to choose from any one reference only so much of it as will support a given position, to exclusion of other parts necessary to full appreciation of what reference fairly suggests to one of ordinary skill in the art.

Particular patents--Polyethylene

Wesslau, Process for the Production of Polyethylene with Narrow Distribution of the Molecular Weight, claims 35 to 43 of application allowed.

Case History and Disposition:

Appeal from Board of Appeals of the Patent Office.

Application for patent of Hermann Wesslau, Serial No. 753,872, filed Aug. 8, 1959; Patent Office Group 140. From decision rejecting claims 35 to 43, applicant appeals. Reversed.

Attorneys:
ARNOLD SPRUNG, New York, N.Y., and ARNOLD B. CHRISTEN, Washington, D. C., for appellant.

CLARENCE W. MOORE (FRED W. SHERLING of counsel) for Commissioner of Patents.

Judge:
Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Associate Judges.

Opinion Text

Opinion By:
ALMOND, Judge.

This appeal is from the decision of the Board of Appeals affirming the rejection of claims 35-43 [1] in appellant's application [2] entitled "Process for the Production of Polyethylene With Narnow Distribution of the Molecular Weight." No claims have been allowed.

The invention relates to a process of polymerizing ethylene utilizing a Ziegler-type catalyst system to produce solid polyethylene. Both appellant and the Patent Office have treated the appealed process claims as standing or falling together, and we will do the same. Claim 35, from which the remaining claims depend, is illustrative and reads as follows:

> 35. In the process of polymerizing ethylene to a solid polymer having a high molecular weight and a narrow molecular weight distribution range, the improvement which comprises polymerizing ethylene in the presence of a polymerization catalyst con
>
> Page 392
>
> sisting essentially of a mixture of titanium trichloride, at least one compound of tetravalent titanium $Ti(R)_4$ and at least one organic aluminum compound soluble in a liquid hydrocarbon and having the general formula $R'Al(R)_2$ in which R' is alkyl and R is selected from the group consisting of halogen, alkoxy and aroxy radicals, wherein between said tetravalent titanium compound and said organic aluminum compound there is present in said mixture at least one halogen atom and at least one member selected from the group consisting of alkoxy and aroxy radicals.

According to appellant's disclosure, polyethylene of high molecular weight may be produced by what has become known in the art as the Ziegler polymerization process. Analysis of the polyethylene so produced has revealed that although the *average* molecular weight of the polymer is high, a fairly large proportion of the individual polymer chains have a relatively low molecular weight. These low molecular weight fractions are particularly unfavorable for such properties as impact bending strength, rubbing, and fatigue. Appellant has discovered that the proportion of the lower molecular weight chains can be reduced, thereby narrowing the molecular weight distribution, by employing a three-component catalyst system in which either the $Ti(R)_4$ or $R'Al(R)_2$ contains an alkoxide or aroxide moiety.

The references relied on are:

Anderson 2,862,917 December 2, 1958

Muehlbauer 2,905,661 September 22, 1959

Ruhrchemie (Belgian) 553,694 June 24, 1957

The Ruhrchemie patent relates to a process for producing polyethylene of a desired molecular weight employing certain specified catalyst systems. The pertinent portion of the patent specification reads as follows:

> * * * when high molecular weight [polyethylene] products are to be obtained * * *, the employed mixtures consist of aluminum alkyl compounds and/or halides of aluminum alkyl with quantities of titanium trichloride of at least 0.01 mole * * * and quantities of titanium tetrachloride lower than 0.01 mole * * *; on the other hand, when materials having low molecular weight are to be obtained the employed mixtures consist of aluminum alkyl and/or halide of aluminum alkyl with more than 0.1 mole * * * of titanium tetrachloride per mole of aluminum alkyl and/or halide of aluminum alkyl, and with titanium trichloride at the rate of at least 0.1 mole, preferably 0.3-1 mole approximately per mole of aluminum alkyl and/or halide of aluminum alkyl.

The Anderson patent relates to a process of polymerizing ethylene whereby control over the weight average molecular weight of the polymer and the *molecular weight distribution* of the polymer is achieved by adhering to process conditions which insure the solubility of the ethylene during polymerization. The process employs coordination catalysts of titanium:

> * * * obtained by admixing a trivalent or tetravalent titanium compound of the class consisting of titanium salts and titanium alkoxides with a compound having at least one metal-to-hydrocarbon bond, such as metal alkyls, suitable compounds being lithium aluminum alkyls, aluminum alkyls, Grignard reagents, alkyl aluminum halides, tin alkyls, etc. * * *

Anderson further states:

> * * * the steady state compliance [an indicia of molecular weight distribution] will vary from 3 to 7 when the critical conditions of the process of the present invention are maintained and will rise to a range of 12 to 28 when the polymerization is carried out at conditions other than required by the process of the present invention. * * *

Muehlbauer relates to a process for producing high molecular weight polyolefins employing a two-component catalyst system consisting of certain metal halides and a compound of the formula $XAlR(OR')$, where X is halogen, and R and R' are the same or different alkyl, cycloalkyl, or aryl radicals. Titanium trichloride and titanium tetrachloride are specifically disclosed as suitable metal halides.

The sole issue in this case is obviousness under 35 U.S.C. 103.

Appellant's principal contention is that:

> * * * since none of the reference[s] either singly or in combination teach a control of the molecular weight distribution range by specific selection of catalyst components, or even that the nature or composition of the catalyst could have an effect on this molecular weight distribution range, the subject matter of the invention as a whole could not possibly be obvious from the references. * * *

We agree. Appellant's specification contains ten examples in which various three-component catalyst systems were utilized in the polymerization of ethylene. The systems set forth in three of these examples consisted of (1) titanium trichloride, (2) titanium tetrachloride, and (3) diethyl aluminum monochloride is various molar ratios. These fall within the catalyst systems disclosed by Ruhrchemie. The U value, which according to appellant's specification is a measure of the molecular weight distribution, ranges from 6.3 to 12.8 for such catalysts. In the remaining seven examples, catalyst systems covered only by the appealed claims were employed, with the nonuniformity value U [3] for the resultant polyethylene ranging from 2.6 to 3.9 We believe this to be a convincing demonstration that the alkoxide or aroxide moiety, when present in the catalyst systems of the appealed claims, possesses the property of conferring a significant degree of control over the ultimate molecular weight distribution of polyethylene. This property is neither taught nor

uggested by the prior art.

The reasoning of the examiner and the board appears to be as follows: Ruhrchemie discloses a titanium trichloride - itanium tetrachloride - mono - ethyl aluminum dichloride system. This differs from appellant's system only in the atter's use of an alkoxide or aroxide group on either the tetravalent titanium or aluminum component or both. Since Anderson shows a tetravalent titanium compound containing an alkoxide group and Muehlbauer shows an aluminum ompound containing an alkoxide group, appellant's catalyst system can be met merely by substitution of such alkoxide groups on the corresponding components of the Ruhrchemie system.

1] The fallacy of this reasoning is that no one of the references *suggests* such a substitution, quite apart from the result vhich would be obtained thereby. Such piecemeal reconstruction of the prior art patents in the light of appellant's lisclosure is contrary to the requirements of 35 U.S.C. 103. In re Rothermel, 47 CCPA 866, 276 F.2d 393, 125 USPQ 328.

2] The ever present question in cases within the ambit of 35 U.S.C. 103 is whether the subject matter as a whole would iave been obvious to one of ordinary skill in the art following the *teachings* of the prior art at the time the invention vas made. It is impermissible within the framework of section 103 to pick and choose from any one reference only so nuch of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The Anderson patent is the only reference before us vhich recognizes the desirability of producing polyethylene with a narrow molecular weight distribution range. Were one to follow the teachings of that patent in its entirety, he would be led to believe that control over the molecular veight distribution of polyethylene was gained independently of the catalyst system, a belief untenable in light of appellant's disclosure.

Both the board and the solicitor apparently assert the position that it is incumbent upon appellant to show that his esults are outstanding as compared with the results accomplished by Anderson and Muehlbauer. If this is construed as equiring appellant to show unexpected results accruing from his claimed process, we think he has met the equirement. We perceive no teaching in the prior art of record suggesting that an alkoxide or aroxide moiety in a Ziegler-type catalytic system would produce the results obtained by appellant's process.

The decision of the board is *reversed.*

Footnotes

Footnote 1. Appellant withdrew the appeal with respect to the only product claim 44, which was drawn to a polyethylene having a narrow nolecular weight distribution characterized by a nonuniformity value U of magnitude between 2 and 4.

Footnote 2. Serial No. 753,872, filed August 8,

Footnote 3. Appellant's specification contains the following description of the nonuniformity value U:

> * * * the so-called non-uniformity is used for characterising the range of distribution of the molecular weights. According to G. V. Schulz in H. A. Stuart's Die Physik der Hochpolymeren, 2nd vol., the macromolecule in solutions is given on page 754 as:
> *Graphic material consisting of a complex mathematical formula set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.*

'M $_w$ and 'M $_n$ can be calculated from the molecular weight distribution by current methods (G. V. Schulz and M. Marx: Makromolekulare Chemie XIV (1954), pages 53-64).

- End of Case -

Print-Friendly Version

Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc. (CA FC) 230 USPQ 416

Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.

U.S. Court of Appeals Federal Circuit
230 USPQ 416

Decided July 14, 1986
No. 85-2578

Headnotes

PATENTS

1. Practice and procedure in Patent and Trademark Office -- Prosecution -- In general

Federal district court erred by holding laser-marked contact lens patent to be invalid, in view of court's failure to grant patent its statutory presumption of validity, its over-reliance upon inventor's alleged opinion as to non-obviousness, its misuse of such opinion as substitute for determining level of skill of hypothetical person of ordinary skill, its use of improper hindsight analysis, its failure to consider prior art reference in its entirety, and its erroneous reliance upon irrelevant experiments.

2. Infringement -- Literal infringement (§ 120.05)

Federal district court erred in its finding of non-infringement of contact lens patent, since court, in considering whether accused lenses were "smooth" like patented lenses, did not construe meaning of term "smooth" by resorting to specification, but instead distorted patent's claims by assessing smoothness according to approach that exceeded level of smoothness required in claim.

Particular patents -- Contact Lenses

4,194,814, Fischer, McCandless, and Hager, Transparent Ophthalmic Lens Having Engraved Surface Indicia, holding of invalidity and non-infringement vacated.

:ase History and Disposition:

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ıppeal from District Court for the Northern District of California, Aguilar, J.; 226 USPQ 780 .

ıction by Bausch & Lomb, Inc., against Barnes-Hind/Hydrocurve, Inc., and Barnes-Hind International, Inc., for patent ıfringement, in which defendants counterclaim for declaration of patent invalidity and non-infringement. From ıdgment for defendants, plaintiff appeals. Vacated and remanded.

\ttorneys:

.aurence H. Pretty, and Pretty, Schroeder, Brueggemann & Clark, both of Los Angeles, Calif. (Craig S. Summers, ;ernard D. Bogdin, and Howard S. Robbins, all of Rochester, N.Y., on the brief) for appellant.

ohn M. Calimafde, and Hopgood, Calimafde, Kalil, Blaustein & Judlowe, both of New York, N.Y. (Eugene J. Kalil,)ennis J. Mondolino, and Gilbert W. Rudman, all of Tuckahoe, N.Y., on the brief) for appellees.

Judge:

;efore Markey, Chief Judge, Friedman, Circuit Judge, and Nichols, Senior Circuit Judge.

Opinion Text

)pinion By:

Jichols, Senior Circuit Judge.

\ppellant Bausch & Lomb, Inc. filed suit in the United States District Court for the North

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rn District or California, alleging that appellee Barnes-Hind/Hydrocurve, Inc. and Barnes-Hind International, Inc. hereinafter Barnes-Hind) infringed patent No. 4,194,814 ('814 patent) in the manufacture and sale of its laser-marked ontact lens. Barnes-Hind denied infringement and counterclaimed that the '814 patent was invalid, void, and ınenforceable. In No. C-83-20283-RPA, Judge Aquilar found the patent invalid for obviousness and not infringed. Ve vacate and remand.

\ppellee Barnes-Hind relied to a large extent on deposition testimony which was never introduced into evidence. ;ecause this testimony was not in evidence, it would have been improper for us to consider it and, therefore, we did ıot. This eliminated much of Barnes-Hind's arguments on appeal.

Background

I. *The Technology*

/ision correcting contact lenses have become familiar; hard contact lenses were introduced in the early 1950's and soft enses in 1971. Toric contact lenses, which correct for the eye condition known as astigmatism, have a similar history)f usage: hard lenses from the early 1950's and soft from the first half of the 1970's. Toric lenses differ from standard ontact lenses in having a prism base, *i.e.*, one edge portion of the lens is thicker. Proper prescription and fitting of oric lenses on the cornea of the eye requires alignment of a central lens axis with this prism base. Markings on the ontact lens surface greatly facilitate the fitting process.

nks and other substances have been used since the early 1950's, however, those marking procedures suffer several lisadvantages: difficulty of accurate application with possible FDA disapproval; possibility of dissolution, blurring, ınd allergic reactions. Mechanical marking, as with a sharp scribing tool or an abrading tool such as a dental bur, is ılso available, but not without its problems: inaccurate and inconsistent positioning of the mark, lens damage, nadequate visibility, and the expense and time involved.

². *The Patent*

The '814 patent, entitled Transparent Ophthalmic Lens having Engraved Surface Indicia, discloses an engraved contact ens and provides a method of engraving using a source of high intensity electro-magnetic energy, such as a laser. The nark, not as deep as the lens is thick, is surrounded by a smooth surface of unsublimated or unaffected polymer naterial with the result that edges of the markings do not inflame or irritate the eyelid of the lens wearer.

The claims in suit are 1, 2, and 7. Claim 1 provides:

An ophthalmic lens adapted to be placed in direct contact with eye tissue formed of a transparent cross-linked polymer naterial, said lens being characterized by identifying indicia engraved in a surface thereof by subjecting said lens to a ɔeam of radiation emerging from a laser having an intensity and wavelength at least sufficient to sublimate said ɔolymer and form depressions in said lens surface to a depth less than the thickness of said lens, said lens having a ;mooth surface of unsublimated polymer material surrounding said depressions, and by varying in a predetermined nanner the point at which said laser beam impinges upon said lens surfaces to engrave said identifying indicia in said ens surface.

Claim 2 depends from claim 1 with the limitation that the lens is formed by a cross-linked hydrophilic (water loving) ɔolymer. Claim 7, a product claim, is similar to claim 1 but defines the depressions as relieved zones.

3. *The Dispute*

In February 1976, Mr. Donald Hager, then production manager at the Milton Roy Company, a manufacturer of soft ɔontact lenses which was purchased by appellant Bausch & Lomb in 1979, sent to Carco, Inc., a distributor of laser ɔquipment, six soft contact lenses for laser marking. At least two lenses were successfully marked. Around September 1976, Dr. David Fisher and Mr. James A. McCandless, also of Milton Roy Company, met with Mr. Hager to debrief him on the work. Soon thereafter, Mr. Hager resigned.

Dr. Fisher and Mr. McCandless continued to work on the lens-marking system, and in November 1977 filed an application for the patent in suit, listing themselves and Mr. Hager as inventors. Mr. Hager declined to execute the patent application, being at that time the employee of another lens manufacturing company, Sauflon International, Inc. and saying that he had not "invented anything in connection with laser marking of contact lens." He further said that he could not execute documents, under oath or otherwise, that represent the contrary. The patent and Trademark Office (PTO) initially, and on a second occasion, rejected all the claims as obvious over two prior art U.S. patents to Brucker (No. 3,833,786) (teaching the use of a laser to fenestrate, i.e., make holes, in contact lens to allow circulation of fluid through the lens) and to Caddell (No. 3,549,733) (disclosing the use of a laser to remove plastic from the surface of a printing plate to form a pattern). The PTO later issued the patent in 1980 as limited to a transparent cross-linked polymer having a smooth surface around the mark. Mr. Hager

did sign as inventor in 1982. Meanwhile, Milton Roy commenced manufacture and marketing of laser-marked soft contact lenses in 1978.

Barnes-Hind's predecessor, Continuous Curve, Inc., introduced under the trademark HYDROCURVE a line of soft toric lenses around 1975-76 that were marked with an indentation by a bur. In 1981, Barnes-Hind offered a soft toric lens marked by a laser.

Bausch & Lomb filed suit, contending that certain laser-marked contact lenses manufactured and sold by Barnes-Hind infringe claims 1, 2, and 7 of the '814 patent. Barnes-Hind denied infringement and counterclaimed that the patent was

nvalid, void, and unenforceable. The parties narrowed the issue of infringement to whether the marks on the HYDROCURVE lenses are surrounded by a smooth surface of unsublimated polymer material with respect to claims 1 and 2 or a smooth and unaffected surface for claim 7.

I. *The District Court Proceedings*

The district court determined that Barnes-Hind "proved by clear and convincing evidence that the patent in suit (4,194,814) and each of its claims is invalid and therefore void." It concluded that the differences between the claims and the prior art would have been obvious, finding that "the fact that the claimed subject matter of the patent in suit was obvious to Mr. Hager is most indicative of the obviousness of the invention," and that "Dr. Brucker's experiments in laser marking contact lenses are further evidence in support of this court's finding of obviousness." The court further concluded that scanning electron microscope (SEM) photographs, showing "that the surface of these lenses surrounding the laser mark are not 'smooth and unsublimated' or 'unaffected' as those terms were defined by plaintiff [appellant] during the processing of the patent in suit," demonstrated lack of infringement in any case. Bausch & Lomb appealed.

Opinion

The judgment is premised on several legal errors: (1) disregard of the presumption of validity established by 35 U.S.C. § 282; (2) absence of the factual findings on the four inquiries mandated by *Graham v. John Deere Co.,* 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); and (3) improper claim construction leading to the conclusion of noninfringement. We vacate the court's opinion and remand for a determination consistent with this opinion.

I. *Presumption of Validity*

A patent shall be presumed valid, and each claim shall be presumed valid independently of the validity of other claims. 35 U.S.C. § 282. The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence. *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 872, 228 USPQ 90, 97 (Fed. Cir. 1985); *Jones v. Hardy,* 727 F.2d 1524, 220 USPQ 1021 (Fed. Cir. 1984).

The record contains no reference to this statutory presumption of validity, nor does it appear that the district court considered separately the validity of the three claims at issue. By merely holding that "defendants have proved by clear and convincing evidence that the patent in suit (4,194,814) and each of its claims is invalid and therefore void," the district court improperly denied the '814 patent its statutory presumption of validity as to each claim.

The district court thought the examiner had been misled. Barnes-Hind argued and argues here that Bausch & Lomb (or rather its later acquired company Milton Roy) misled the examiner during prosecution. Appellees assert that "if the examiner had been correctly and forthrightly informed of Hager's and McCandless' opinions, the chemistry of the Brucker lens, and the teaching of the Caddell patent, he would not have issued the patent." The record, however, does not support this assertion.

The examiner did know of Hager's temporary refusal to execute the application during prosecution and, as discussed more fully *infra,* a determination of nonobviousness is based, *inter alia,* on the opinion of a hypothetical person of ordinary skill in the art, not on the inventors' opinion. The weight to be attached to Hager's refusal cannot be exaggerated as the court below has done without clear error in view of Hager's self interest as an employee of a competitor and his later change of position. Instances of inventors refusing even to cooperate in obtaining issuance of a patent to be owned by an assignee are common and machinery is provided in 37 C.F.R. § 1.47 to deal with them. Section 1.47 provides that either a joint inventor or a proper assignee may file the application without the consent or signature of the inventor, just so the oath or declaration is accompanied by a petition including proof of pertinent facts. It is clear, therefore, that the PTO does not allow the inventor to erect that type of obstacle to obtaining patent protection. Such forethought is necessary, as otherwise an inventor's changed self interest might nullify a proper assignment. The district court's heavy reliance on Mr. Hager's assertions, if persisted in, would allow a co-inventor another chance at sabotage if the first effort has failed.

Finally, the examiner, who with the deference we owe governmental officials we assume has some expertise in interpreting the refer

:nces and some familiarity with the level of skill in the art, *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359, 220 USPQ 763, 770 (Fed. Cir.), *cert. denied*, ___ U.S. ___, 105 S.Ct. 95, 224 USPQ 520 (1984), did have the Brucker and Caddell patents before him. Barnes-Hind's "misleading the examiner" contention is insufficiently supported to overcome the presumption of validity.

As a final matter, we recognize, as the district court did not, that when the prior art before the court is the same as that before the PTO, the burden on the party asserting invalidity is more difficult to meet. *American Hoist*, 725 F.2d at 1359, 220 USPQ at 770.

2. *Graham Findings*

Obviousness under 35 U.S.C. § 103 is a question of law based on the underlying factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of secondary considerations. *See, e.g., Loctite*, 781 F.2d at 872, 228 USPQ at 97-98.

The *Loctite* court further stated:

In patent cases, the need for express *Graham* findings takes on an especially significant role because of an occasional tendency of district courts to depart from the Graham test, and from the statutory standard of obviousness that it helps determine, to the tempting but forbidden zone of hindsight. Thus we must be convinced from the opinion that the district court actually applied *Graham* and must be presented with enough express and necessarily implied findings to know the basis of the trial court's opinion.

Id, 228 USPQ at 98.

Here, as in *Loctite* and in *Jones*, we are not convinced that the district court applied the *Graham* findings. Instead, it found Mr. Hager's opinion that the subject matter was obvious "most indicative of the obviousness of the invention." This was legal error.

Unlike the district court, we have the benefit of the very clear exposition of the law in *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454, 227 USPQ 293, 297-98 (Fed. Cir. 1985):

The issue of obviousness is determined entirely with reference to a *hypothetical* "person having ordinary skill in the art." It is only that hypothetical person who is presumed to be aware of all the pertinent art. The actual inventor's skill is irrelevant to this inquiry, and this is for a very important reason. The statutory emphasis is on a person of *ordinary* skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something -- call it what you will -- which sets them apart from the workers of *ordinary* skill, and one should not go about determining obviousness under § 103 by inquiring into what *patentees* (i.e., inventors) would have known or would likely have done, faced with the revelation of references. [Emphasis in original.]

[1] In this regard then, the district court erred at least three times: it relied too heavily on the alleged opinion of one who was an inventor and patentee, and misused that opinion as a substitute for determining the level of skill of the hypothetical person of ordinary skill and what that person would have been able to do when in possession of the prior art, the scope and contents of which the court should also have determined.

The court also engaged in improper hindsight analysis to conclude the '814 patent would have been obvious. The court essentially adopted Barnes-Hind's argument that "the concept of forming ridgeless depressions having smooth rounded edges using a laser beam to vaporize the material is explicitly disclosed in the Caddell patent. *This is exactly the same process claimed in the patent-in-suit and practiced by the plaintiff.*"

Barnes-Hind selected a single line out of the Caddell specification to support the above assertion: "one way in which this [forming ridgeless depressions] can be achieved is to use a laser with high enough intensity to vaporize the plate material without melting it." Col. 5, lines 53-54. This statement, however, was improperly taken out of context. As the

ormer Court of Customs and Patent Appeals held:

t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it is will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference 'airly suggests to one skilled in the art.

'n re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); *see also In re Mercer,* 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975).

A full appreciation of Caddell's statement requires consideration of the immediately following sentences in the same paragraph and the paragraph after that. Viewed in that context, it is apparent that Caddell's ideal printing plate would have no ridges around the depression. The use of a high intensity laser is offered as a possible means to achieve the goal but is limited by several disadvantages. To overcome these disadvantages, Caddell suggests the use of a special class of polymer that forms ridgeless depressions. A complete read

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ing demonstrates quite clearly that Caddell is setting up a strawman and pointing out its disadvantages to highlight the advantages of Caddell's invention, that special class of polymers. The district court improperly viewed an isolated line in Caddell in light of the teaching of the '814 patent to hold for obviousness. This is improper hindsight analysis.

The district court also failed to consider the Caddell reference in its entirety and thereby ignored those portions of the reference that argued against obviousness. *W. L. Gore & Associates, Inc. v. Garlock, Inc.,* 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed. Cir. 1983), *cert. denied,* ___ U.S. ___, 105 S. Ct. 172 (1984). Caddell compared the ridge formation of his special class of polymers against, *inter alia,* Lucite, a copolymer composed of ethyl acrylate with methylmethacrylate -- very similar to the chemical referred to in the '814 patent -- and found that *only* his special class formed depressions without ridges. Thus, Caddell actually taught away from laser etching of soft contact lenses.

As further evidence of obviousness, the district court relied on Dr. Brucker's experiments in laser marking contact lenses. This too was error, in this case clearly erroneous factual error. The record does not support, indeed it contradicts, the supposition that Dr. Brucker had engaged in laser marking of soft contact lenses at the time of the present invention. On page 385 of the Appendix, in reply to Mr. Calimafde's question "when did Continuous Curve begin to experiment with laser marking of soft contact lenses?", Dr. Brucker replied "I believe it was in '79 -- '79, '80, somewhere in that area." The filing date of the '814 patent was November 10, 1977. Brucker's 3,833,786 patent for a method of fenestrating (putting windows in) contact lenses applies according to its claims to such lenses, both soft and hard. However, the record reflects that the need for such fenestration was as a mode of escape for fluid accumulating between the lens and the eye. Such a need does not exist respecting the soft lenses, the principal subject of the claims in suit, of which claim 2 is expressly limited to soft lenses. They, being hydrophilic, absorb the fluid.

In sum, the district court improperly determined the '814 patent was obvious: it failed to make the Graham inquiries, it improperly focused on what was obvious to the inventor, it engaged in hindsight analysis, and it considered evidence that was not prior art. This court, as an appellate court, may not make the required Graham factual findings, and must therefore remand that determination to the district court. The district court should not ignore the four-part analysis the authorities require.

a. *The scope and content of prior art*

To determine whether a reference is within the scope and content of the prior art, first determine if the reference is within the field of the inventor's endeavor. If it is not, then next consider whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Richard M. Deminski,* 230 USPQ 313, 315, No. 85-2267, slip op. at 9 (Fed. Cir. July 8, 1986); *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). *Orthopedic Equipment Co., Inc. v. United States,* 702 F.2d 1005, 1008-11, 217 USPQ 193, 196-97 (Fed. Cir. 1983) focused on the claims in suit, the art the PTO applied to the claims, and the nature of the problem confronting the inventor. Further, the art must have existed as of the date of invention, presumed to be the filing date of the application until an earlier date is proved.

b. *The differences between the claimed invention and the prior art*

The court must view the claimed invention *as a whole. See, e.g., Jones,* 727 F.2d at 1527-28, 220 USPQ at 1024. We add, as a cautionary note, that the district court appeared to distill the invention down to a "gist" or "core," a superficial mode of analysis that disregards elements of the whole. It disregarded express claim limitations that the product be an ophthalmic lens formed of a transparent, cross-linked polymer and that the laser marks be surrounded by a smooth surface of unsublimated polymer. *See also, ACS Hospital Systems, Inc. v. Montefiore Hospital,* 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984).

c. *Level of ordinary skill in the art*

In *Environmental Designs, Ltd. v. Union Oil Co.,* 713 F.2d 693, 697, 218 USPQ 865, 868-69 (Fed. Cir. 1983), *cert. denied,* 464 U.S. 1043 (1984), the court listed six factors relevant to a determination of the level of ordinary skill: educational level of the inventor, type of problems encountered in the art, prior art solutions, rapidity of innovation, sophistication of technology, and educational level of active workers in the field. As to educational level of the inventor, *see Standard Oil Co. v. American Cyanamid Co.,* 774 F.2d 448, 227 USPQ 293 (Fed. Cir. 1985); *Orthopedic Equipment Co. v. All Orthopedic Appliances,* 707 F.2d 1376, 1382, 217 USPQ 1281, 1285 (Fed. Cir. 1983) ("Although the educational level of the inventor may be a factor in determining the level of ordinary skill in the art, it is by no means conclusive.")

d. *Objective indicia of obviousness*

Such "secondary considerations," when present, must always be considered. Stratoflex, 713 F.2d at 1538, 218 USPQ at 878-79. *See also Cable Electric Products, Inc. v. Genmark,*

Inc., 770 F.2d 1015, 1026-28, 226 USPQ 881, 887-88 (Fed. Cir. 1985). Such evidence includes commercial success, long felt but unresolved needs, and failed attempts. *Perkin-Elmer Corp. v. Computervision Corp.,* 732 F.2d 888, 895-96, 221 USPQ 669, 675 (Fed. Cir.), *cert. denied,* ___ U.S. ___, 105 S.Ct. 187, 225 USPQ 792 (1984).

We shall vacate the trial court's opinion and remand for an obviousness determination consistent with this opinion.

3. *Infringement*

The parties narrowed the infringement issue for trial to the question whether the surface of Barnes-Hind lenses surrounding the laser mark is "smooth and unsublimated" or "unaffected." The district court concluded that "the laser-engraved depressions in the surface of the HYDROCURVE II lenses have been examined by scanning electron microscope. These photographs show that the surface of these lenses surrounding the laser mark are not 'smooth and unsublimated' or 'unaffected' as those terms were defined by plaintiff during the prosecution of the patent in suit." Appellant Bausch & Lomb argues on appeal that the trial court's approach of assessing smoothness at the very high levels of magnification obtainable by a SEM exceeds the level of smoothness required in the claims. We agree.

Because the first step in determining infringement is claim construction, improper claim construction can distort the entire infringement analysis. *Moeller v. Lonetics, Inc.,* 229 USPQ 992, 994, No. 85-2646, slip op. at 7 (Fed. Cir. June 4, 1985). Such a distortion occurred below.

Disputed issues such as the meaning of the term "smooth," should be construed by resort to extrinsic evidence such as the specification, other claims, and the prosecution history. Here, resort to the specification clearly demonstrates that "smooth" meant that "the edges of the craters neither inflame nor irritate the eyelid of the lens wearer * * *. The markings provided on the lens surface in accordance with this invention * * * are not perceived by the lens wearer * * *." The prosecution history supports this construction. A reading of the amendment and its accompanying remarks demonstrates that smooth means the absence of a ridge that "would scratch either the eye or eyelid and would lead to infection." There is no indication that smooth means absolutely ridge-free. (This review of the prosecution history also leads us to disagree with Barnes-Hind's final argument that the prosecution history estops Bausch & Lomb from

sserting infringement against the allegedly ridged HYDROCURVE lens.) Testimony from Dr. Mandell, Bausch & omb's expert in the field of contact lenses, indicates that to a person of ordinary skill in the art, smooth would mean an bsence of "roughness or significant elevation" so that a wearer "would not feel it with the [eye]lid." Further, there is :stimony that a person of ordinary skill in the art would use an optical microscope, not an SEM, to gauge the relative moothness of an etched contact lens.

2] We hold that smooth means smooth enough to serve the inventor's purposes, *i.e.*, not to inflame or irritate the eyelid f the wearer or be perceived by him at all when in place. Accordingly, we vacate the district court's conclusion that ıe surface of the HYDROCURVE lenses are not smooth or unaffected, and remand for a determination of ıfringement based on the proper construction of and proper test for smooth.

Conclusion

Ve vacate the district court's determination that the '814 patent is invalid and remand for a reconsideration of validity ı light of the presumption of validity and the *Graham* findings on obviousness. We further vacate the decision of oninfringement and remand for proper claim construction and infringement analysis.

VACATED AND REMANDED

- End of Case -

Print-Friendly Version

In re Gorman (CA FC) 18 USPQ2d 1885

In re Gorman

U.S. Court of Appeals Federal Circuit
18 USPQ2d 1885

Decided May 13, 1991
No. 90-1362

Headnotes

PATENTS

1. Patentability/Validity - Obviousness - Combining references (§ 115.0905)

Patent and Trademark Office's reliance on teachings of large number of references in rejecting patent application for obviousness does not, without more, weigh against holding of obviousness on appeal, since criterion is not number of references, but whether references are in fields which are same as or analogous to field of invention, and whether their teachings would, taken as whole, have made invention obvious to person skilled in that field.

2. Patentability/Validity - Construction of claims (§ 115.03)

Patentability/Validity - Obviousness - In general (§ 115.0901)

Claim which describes features of invention in great detail is nevertheless obvious in view of prior art, since claim that is narrowly and specifically drawn must still meet requirements of 35 USC 103, and details listed in claim are shown in references and thus do not contribute to unobviousness.

3. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (§ 115.0903.03)

Patentability/Validity - Obviousness - Combining references (§ 115.0905)

application claim for candy sucker on stick, molded in elastomeric mold in shape of human thumb, is obvious in view f prior art, since all elements of claim, including molded lollipop having chewing gum base plug, with elastomeric old serving as product wrapper, and candy in shape of human thumb, are shown in prior art references in various ubcombinations, used in same manner and for same purpose as in claimed invention.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Jeffrey B. Gorman and Marilyn Katz, serial no. 06/882,480 (composite food product). From decision of Board of Patent Appeals and Interferences upholding examiner's rejection of all claims in application, pplicants appeal. Affirmed.

Attorneys:
Thomas W. Tolpin, Highland Park, Ill., for appellant.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor, with him on brief), for appellee.

Judge:
Before Rich, Newman, and Rader, circuit judges.

Opinion Text

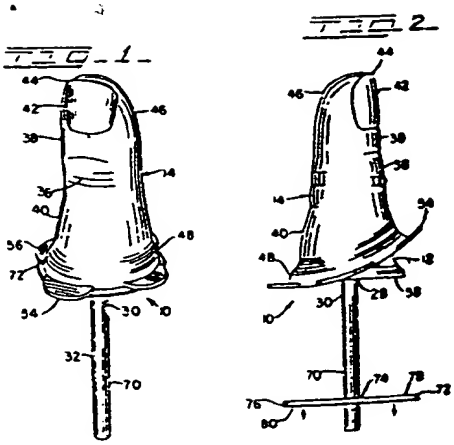
Opinion By:
Newman, J.

effrey B. Gorman and Marilyn Katz (hereinafter "Gorman") appeal the decision of the United States Patent and Trademark Office, Board of Patent Appeals and Interferences (the "Board") denying patentability to all the claims of Gorman's patent application Serial No. 06/882,480, entitled "Composite Food Product." We affirm.

The Invention

The claimed invention is a composite candy sucker on a stick, molded in an elastomeric mold in the shape of a human humb. During the manufacturing process liquid candy is poured into the mold, and an edible plug of bubble or chewing gum or chocolate or food-grade wax is poured into the mold after the candy has hardened, serving as a seal for he end portion of the candy. A paper or plastic disc abuts and covers the plug. The mold serves as a cover that can be emoved from the candy by means of protruding flanges. The cover is described as a "toy and novelty item".

Figure 1 shows the invention in the form in which it is marketed. Figure 2 shows the cover partially removed to reveal he candy portion (12) and the chewable or edible plug (58):



The claims describe the product in detail, as is apparent from claim 16, the claim pressed by Gorman in this appeal:

16. A composite food product, comprising:

a candy core, said candy core being in a generally liquified form when formulated,

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heated, blended and poured into a mold and in a substantially thumb-shaped hardened form when cooled and removed from said mold;

said thumb-shaped hardened form comprising said candy core positioned along a vertical axis and comprising a rigid joint-shaped portion, a rigid upper portion extending upwardly from said rigid joint-shaped portion along said vertical axis, and a rigid lower portion extending downwardly from said rigid joint-shaped portion along said vertical axis, said upper portion having a rigid finger nail-shaped portion with an upper rigid tip providing a rigid top end of said thumb-shaped hardened form and a rigid convex back extending rearwardly and downwardly from said rigid tip, and said rigid lower portion having a rigid bottom end and defining a recessed opening comprising a handle-receiving socket about said vertical axis;

a removable resilient shell comprising a substantially thumb-shaped, elastomeric material selected from the group consisting of rubber and flexible plastic, said shell providing

a mold for receiving and molding said liquified candy form,

a removable outer protective cover positioned about and covering said hardened form comprising said candy core,

a toy and novelty item for placement upon the thumb of the user when removed from said hardened form comprising said candy core;

said thumb-shaped elastomeric material comprising said removable resilient shell comprising a flexible joint-shaped portion, a flexible upper portion extending upwardly from said flexible joint-shaped portion along said vertical axis, and a flexible lower portion extending downwardly from said flexible joint-shaped portion along said vertical axis, said upper portion having a flexible finger nail-shaped portion with an upper flexible tip providing a flexible top end of said shell and a flexible convex back extending rearwardly and downwardly from said flexible tip, and said flexible lower portion having an enlarged open ended diverging base, said base having a larger circumference and transverse cross-sectional area than other portions of said shell and providing the bottom of said shell, said open ended base defining a plug-receiving chamber and an access opening for entrance of said liquified form and discharge of said hardened candy form, and a set of substantially symmetrical arcuate lobes extending radially outwardly from said base, said lobes being circumferentially spaced from each other and providing manually grippable flange portions to facilitate manual removal of said shell from said core;

a plug positioned in said plug-receiving chamber adjacent said bottom of said shell, said plug abutting against the

›ottom of said core and providing a cap ior substantially plugging and sealing the open end of said mold and cover to ıelp enclose said candy core, and said plug comprising a food grade material selected from the group consisting of ›ubble gum, chewing gum, chocolate, and food grade wax;

ı handle having a connecting portion connected to said plug and said candy core and positioned in said plug-receiving ›pening and having a manually grippable handle portion extending downward from said connecting portion along said 'ertical axis; and

ı substantially planar annular disk for abuttingly engaging and removably seating against said base and said lobes ıdjacent said plug, said disk defining a central axial hole for slidably receiving said handle portion and having an outer :dge with a maximum span larger than said access opening but less than the maximum diameter of said symmetrical set ›f lobes to substantially minimize the interference with manually gripping of said manual grippable flange portions of :aid lobes, said disk being of a material selected from the group consisting of paper, paperboard, and plastic, and ›roviding a removable closure member and seal for substantially closing said access opening and sealing said plug and :aid candy core within said shell.

The claims were rejected in view of thirteen references. The primary references, patents to Siciliano, Copeman, and Pooler, show ice cream or candy molded in a plastic, rubber or elastomeric mold. In Siciliano and Copeman the mold ılso serves as the product wrapper. In Siciliano the ice cream is poured into the mold, a stick is inserted, the ice cream s hardened, and a cardboard cover seals the area between the stick and the elastomeric wrapper. Copeman and Kuhlke ;how candy lollipops molded in elastomeric molds. Copeman states that the mold may take "varying shapes, such as in he form of fruit, or animals" and Kuhlke discusses the desirability of sealing candy from the outside air. In Siciliano, Copeman and Kuhlke, the mold is peeled from the confection prior to use.

The two Nolte patents teach that gripping flanges may be placed on an ice cream wrap

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›er to facilitate removal. Ahern and Knaust each show a disc-shaped seal or cover for a frozen confection. Ahern ;hows the cover in conjunction with ice cream on a stick.

Harris shows a hollow thumb-shaped lollipop into which the thumb is inserted, and Craddock shows a thumb-shaped :onfection supported on a disc-shaped handle; in both cases without the other elements shown by Gorman. Fulkerson ;hows a candy coating surrounding a block of ice cream, and a candy plug for retaining liquid syrup inside a cavity in :he ice cream. Webster shows chewing gum entirely enclosing a liquid syrup product. Spiegel shows a chocolate layer ıaving an alcohol diffusion barrier to plug the end of a plastic container of liqueur. Fulkerson, Webster and Spiegel all ;uggest the greater appeal to consumers of providing two different components in the same confection.

The Board found that all of the features of Gorman's product were known to the art, and that various combinations of :hese elements existed in known similar structures. The Board concluded that the applicant's claimed combination was ;uggested by and would have been obvious in light of the references.

Discussion

A

Each element of the Gorman claims is in the prior art, separately or in sub-combination. Gorman argues that when it is necessary to combine the teachings of a large number of references in order to support a rejection for obviousness ınder 35 U.S.C. §103, this of itself weighs against a holding of obviousness.

[1] The criterion, however, is not the number of references, but what they would have meant to a person of ordinary ;kill in the field of the invention. In *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 USPQ 31, 93 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987), the court held that a combination of about twenty references that "skirt[ed] all around" the claimed invention did not show obviousness. In other instances, on other facts, we have ıpheld reliance on a large number of references to show obviousness. Compare *In re Miller*, 159 F.2d 756, 758-58, 72 USPQ 512, 514-15 (CCPA 1947) (rejecting argument that the need for eight references for rejection supported

patentability) with *Kansas Jack, Inc. v. Kuhn,* 719 F.2d 1144, 1149, 219 USPQ 857, 860 (Fed. Cir. 1983) (where teachings relied upon to show obviousness were repeated in a number of references, the conclusion of obviousness was strengthened). *See also, e.g., In re Troiel,* 274 F.2d 944, 947, 124 USPQ 502, 504 (CCPA 1960) (rejecting appellant's argument that combining a large number of references to show obviousness was "farfetched and illogical").

Determination of whether a new combination of known elements would have been obvious to one of ordinary skill depends on various facts, including whether the elements exist in "analogous art", that is, art that is reasonably pertinent to the problem with which the inventor is concerned. *In re Deminski,* 796 F.2d 436, 442, 230 USPQ 313, 315 Fed. Cir. 1986). When the references are all in the same or analogous fields, knowledge thereof by the hypothetical person of ordinary skill is presumed, *In re Sernaker,* 702 F.2d 989, 994, 217 USPQ 1, 5 (Fed. Cir. 1983), and the test is whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention. *See In re Young,* 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

When it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation in the prior art to make the selection made by the applicant. *Interconnect Planning Corp. v. Feil,* 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). "'Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.'" *In re Bond,* 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990) (quoting *Carella v. Starlight Archery and Pro Line Co.,* 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed. Cir. 1986)).

The extent to which such suggestion must be explicit in, or may be fairly inferred from, the references, is decided on the facts of each case, in light of the prior art and its relationship to the applicant's invention. As in all determinations under 35 U.S.C. §103, the decisionmaker must bring judgment to bear. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. *Interconnect Planning,* 774 F.2d at 1143, 227 USPQ at 551. The references themselves must provide some teaching whereby the applicant's combination would have been obvious.

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B

Gorman argues that the references showing ice cream in a mold or wrapper on a stick and the references showing candy in a mold or wrapper on a stick are not analogous, for they require different conditions of production. However, the Copeman reference shows the close relationship of these arts, stating that his elastomeric mold may be used for "frozen confections and other solid confections". We conclude that the ice cream on a stick and candy on a stick arts are analogous, and that the Siciliano, Copeman, Pooler, and Kuhlke references show or suggest Gorman's candy on a stick and covered with an elastomeric mold, for which the thumb-shape is shown by Harris or Craddock.

The suggestion of providing a layer of chewing gum, chocolate or the like, surrounding the candy core in the area not covered by the mold, to seal the candy and provide a second food product, is provided by Fulkerson, Webster, or Spiegel. The paper disc adjacent the base of the candy structure is shown in Ahern and Knaust. Harris and Craddock both show thumb-shaped candy. Gorman argues that the prior art does not suggest using the thumb-shaped cover as a toy after the candy is removed. However, Copeman states that his rubber mold may be used as a "toy balloon" after the candy is removed. Gorman argues that Craddock teaches away from the claimed invention because of Craddock's admonition that lollipops on sticks are dangerous to children. However, candy on a stick is too well known for this caution to contribute to unobviousness.

[2] Claim 16 recites details such as a "joint-shaped portion", a "finger nail portion", an "upper portion", a "lower portion" and a "convex back", as descriptive of the thumb shape. Such details are shown in the references and do not contribute to unobviousness. A claim that is narrowly and specifically drawn must nevertheless meet the requirements of §103:

The mere fact that a claim recites in detail all of the features of an invention (i.e., is a "picture claim") is never, in itself,

justification for the allowance of such a claim.

Manual of Patent Examining Procedure, §706 (Rev. 6, Oct. 1987) at p. 700-6; *In re Romito,* 289 F.2d 518, 129 USPQ 59 (CCPA 1961) (rejecting a "picture claim").

3] Applying the principles of *Graham v. John Deere & Co.,* 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), we discern all of the elements of claim 16, used in substantially the same manner, in devices in the same field of endeavor. The various elements Gorman combined: the molded lollipop with a chewing gum plug, with the mold serving as the product wrapper; and candy in the shape of a thumb; are all shown in the cited references in various sub-combinations, used in the same way, for the same purpose as in the claimed invention. The Board did not, as Gorman argues, pick and choose among isolated and inapplicable disclosures in the prior art. Rather, the claim elements appear in the prior art in the same configurations, serving the same functions, to achieve the results suggested in prior art. *In re Sernaker,* 702 F.2d at 994, 217 USPQ at 5. The large number of cited references does not negate the obviousness of the combination, for the prior art uses the various elements for the same purposes as they are used by appellants, making the claimed invention as a whole obvious in terms of 35 U.S.C. §103.

The Board's decision is *AFFIRMED.*

- End of Case -

Print-Friendly Version

In re Dow Chemical Co. (CA FC) 5 USPQ2d 1529

In re Dow Chemical Co.

U.S. Court of Appeals Federal Circuit
5 USPQ2d 1529

Decided January 25, 1988
No. 87-1406

Headnotes

PATENTS

1. Patentability/validity -- Obviousness -- Evidence of _

Patentability/validity -- Obviousness -- Secondary considerations (§ 115.0907)

Board of Patent Appeals and Interferences erred in rejecting as obvious claims for invention of impact resistant rubber-based resin suitable for molding and extrusion containing preferred ingredients styrene, maleic anhydride, and synthetic diene rubbers, since none of prior art references cited by patent holder and PTO suggest that any process could be used successfully in such three-component system to produce resin having desired properties, and since board did not give fair evidentiary weight to expert's skepticism concerning invention, or to five to six years necessary to produce invention, in determining obviousness issue.

Particular Patents -- Chemical -- Rubber Based Resins

3,919,354, Moore, Lehrer, Lyons and McKeever, impact resistant polymers of a resinous copolymer of an alkenyl aromatic monomer and unsaturated dicarboxylic anhydride, holding of obviousness reversed.

Case History and Disposition:

Appeal from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

Reexamination of Patent No. 3,919,354, held by The Dow Chemical Company. From decisions rejecting all claims of patent as obvious, patent holder appeals. Reversed.

Attorneys:
Douglas N. Deline, Midland, Mich. (Berndt W. Sandt with him on the brief) for appellant.

John H. Raubitschek, associate solicitor, Arlington, Va. (Joseph F. Nakamura, solicitor, and Fred E. McKelvey, deputy solicitor, with him on the brief) for appellee.

Judge:
Before Smith, Nies, and Newman, Circuit Judges.

Opinion Text

Opinion By:
Newman, Circuit Judge.

Dow Chemical Company appeals the decisions of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, No. 86-3426 (Feb. 25, 1987) and No. 662-81 (Mar. 25, 1986), together rejecting all the claims on reexamination of United States Patent No. 3,919,354 entitled "Impact Resistant Polymers of a Resinous Copolymer of an Alkenyl Aromatic Monomer and an Unsaturated Dicarboxylic Anhydride.". We reverse.

The Rejection

The invention is an impact resistant rubber-based resin having improved resistance to heat distortion. Claim 28, the broadest claim on appeal, is illustrative:

28. A polymer suitable for molding and extrusion, of substantially improved resistance to mechanical shock and impact, the polymer consisting essentially of the polymerization product of

a. a monovinyl alkenyl aromatic monomer containing up to 12 carbon atoms and having the alkenyl group attached directly to the benzene nucleus, the al

kenyl aromatic compound being present in a proportion of from about 65 to 95 parts by weight and from 35 to 5 parts by weight of an unsaturated dicarboxylic acid anhyride readily copolymerizable therewith, and

b. from 5 to 35 parts by weight of a diene rubber per 100 parts of (a) plus (b), the rubber consisting essentially of 65 to 100 weight percent butadiene, or isoprene and up to 35 weight percent of an alkenyl aromatic hydrocarbon as the sole other monomer in the rubber, the rubber having a glass temperature not higher than 0° C., the rubber being in the form of a plurality of particles having diameters within the range of 0.02 to 30 microns dispersed throughout a matrix of polymer of alkenyl aromatic monomer and the anhydride, at least a major portion of the rubber particles containing distinct occlusions of the polymer of (a), with the further limitation that

the polymer of (a) is a nonequimolar random copolymer.

The preferred ingredients are styrene, maleic anhydride, and synthetic diene rubbers, and our discussion will be in these terms, as was the Board's.

The Board's decision that the claimed invention would have been obvious in terms of 35 U.S.C. §103 was based on the combination of two references: a 1966 article by Molau and Keskkula entitled "Heterogeneous Polymer Systems IV. Mechanism of Rubber Particle Formation in Rubber-Modified Vinyl Polymers", and Baer U.S. Patent No. 2,971,939. Also discussed were Farmer U.S. Patent No. 2,275,951 and a publication by Bacon and Farmer entitled "The Interaction of Maleic Anhydride with Rubber", although the Board stated that the rejection was sustainable without relying on either of these references.

The Prior Art

The Molau/Keskkula article shows the preparation of a resin having high impact strength by dissolving synthetic diene rubber in styrene and polymerizing the styrene. This reference teaches that phase inversion is necessary to the formation of these moldable, extrudable resins. Baer prepares nonequimolar random maleic anhydride-styrene copolymers by a technique whose salient feature is adding the maleic anhydride slowly to polymerizing styrene under controlled conditions.

Farmer shows the reaction among natural rubber, styrene, and maleic anhydride, and also states that maleic anhydride reacts directly with the rubber. The Bacon and Farmer article also shows the reaction of maleic anhydride with natural rubber. These products, according to Dow's evidence and as found by the Board, do not have a dispersed rubber phase containing occlusions, and are not moldable.

Dow argues that the Board has engaged in hindsight reconstruction of the claimed invention. To support its position Dow refers to several scientific publications and other references, in addition to those cited by the PTO, and evidence submitted by declaration and deposition.

The first group of references to which Dow refers shows the reaction of maleic anhydride with natural or synthetic rubbers. These references show both intermolecular and intramolecular reactions between maleic anhydride and the various rubbers, but not a grafted rubber, which is said by Dow to characterize its product. Additional references are cited by Dow to show that maleic anhydride is much more reactive with diene-type synthetic rubbers than with natural rubber, and that the reaction with the synthetic rubbers is difficult to control and the product is unpredictable.

Another reference cited by Dow, the *Encyclopedia of Science and Technology* , states the general rule, derived from experience with acrylonitrile, that copolymers with synthetic diene rubbers have elevated glass transition temperatures; Dow advises that this is a highly undesirable property for a high-impact strength resin.

Another series of references cited by Dow shows several known techniques of reacting styrene and maleic anhydride to prepare nonequimolar copolymers, all different from the technique shown in the Baer patent.

Analysis

The Board held that the claimed product results from the application of the Baer technique to a styrene-maleic anhydride polymer system which includes synthetic diene rubber, and that it would have been obvious to do that which these inventors did if one wanted to increase the heat stability of a known high impact styrene rubber resin.

The crux of Dow's argument is that no reference shows or suggests that these references should or could be combined successfully. Indeed, the Board agreed, stating that "[i]t is not apparent from the evidence whether rubber and maleic anhydride would have been expected to react *in the process suggested by the combined disclosure of Molau and Baer* . . ." (Emphasis in original).

Dow also points out, referring to the Keskkula evidence, that it was believed that these products could not be made by

he mass polymerization techniques of the prior art. Dow asserts that no reference, including Baer, suggested that the Baer technique could produce the requisite phase inversion in a system containing diene rubber, and could produce a diene-rubber containing resin that could be molded and had the other desired high-impact and thermal properties.

Dow refers to the Farmer patent, cited by the examiner and the Board, which shows that the reaction of styrene, maleic anhydride, and natural rubber forms a product that is unsuitable as a molding resin. Dow argues that Farmer leads away from the Dow invention, in that Farmer obtains precisely the "runaway" reaction, and undesirable product, that Keskkula believed was characteristic of reactions involving styrene, maleic anhydride, and rubbers. Dow points to Dr. Keskkula's Report to Dow management, written in 1966 at about the time the present invention was made, pointing out the many problems in attempting to produce the three-component product that these inventors later succeeded in producing.

In response, the Commissioner argues that even though an expert polymer scientist, Dr. Keskkula, "personally may have been surprised by the invention at the time it was made, it does not necessarily follow that the invention would have been unobvious to one of ordinary skill in the art." The Commissioner suggests that one less encumbered by knowledge of the need for phase inversion, as described in the Molau/Keskkula article, might have achieved the Dow product by combining the references in the way suggested by the Commissioner. Reflecting on this theory of invention, we observe that such a person did not do so, despite the decades of experimentation with these components, and the recognition of need, as evidenced by the many references cited by both sides. *See In re Geiger* , 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *ACS Hospital Systems, Inc. v. Montefiore Hospital* , 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).

The Board held that Dow's statement in the patent specification that it was known that styrene/maleic anhydride copolymers had improved heat resistance as compared with styrene rubbers, made it prima facie obvious to combine these three components. Indeed, the record shows that such combinations had previously been made, in various ways, but without producing the product here desired. That there were other attempts, and various combinations and procedures tried in the past, does not render obvious the later successful one. The PTO's reliance on Dow's "admission" of longfelt need as prima facie evidence of obviousness is contrary to logic as well as law. Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness. *Graham v. John Deere Co* ., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *Custom Accessories v. Jeffrey-Allan Industries* , 807 F.2d 955, 960, 1 USPQ2d 1196, 1199 (Fed. Cir. 1986). Further, a patent applicant's statement of the purpose of the work is not prior art.

The Board thus concluded that although one would not know in advance whether the Baer technique would work at all in the presence of diene rubber, or produce a moldable high-impact product, if it did succeed it would have been obvious. The Board criticized Keskkula's evidence for not stating whether, after these inventors proposed the procedure here at issue, Keskkula would have expected the maleic anhydride to react preferentially with the diene rubber or with the styrene and to what effect on the impact properties of the product. The PTO argues that unless the prior art is shown to have led one of ordinary skill to expect the Baer technique to fail, the applicant's burden is not met. This is not the criterion. That these inventors eventually succeeded when they and others had failed does not mean that they or their colleagues must have expected each new idea to fail. Most technological advance is the fruit of methodical, persistent investigation, as is recognized in 35 U.S.C. §103 ("Patentability shall not be negatived by the manner in which the invention was made").

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. *See Burlington Industries v. Quigg* , 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed. Cir. 1987); *In re Hedges* , 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed. Cir. 1987); *Orthopedic Equipment Co. v. United States* , 702 F.2d 1005, 1013, 217 USPQ 193, 200 (Fed. Cir. 1983); *In re Rinehart* , 531 F.2d 1048, 1053-54, 189 USPQ 143, 148 (CCPA 1976). Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered; for the person of ordinary skill is charged

vith knowledge of the entire body of technological literature, including that which might lead away from the claimed nvention. The Commissioner argues that since the PTO is no longer relying on Farmer or the Bacon and Farmer rticle, the applicant is creating a "straw man". It is indeed pertinent that these references teach against the present nvention. Evidence that supports, rather than negates, patentability must be fairly considered.

1] The PTO presents, in essence, an "obvious to experiment" standard for obviousness. However, selective hindsight s no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a eason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's lisclosure. *Interconnect Planning Corporation v. Feil* , 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). Of he many scientific publications cited by both Dow and the PTO, none suggests that any process could be used uccessfully in this three-component system, to produce this product having the desired properties. The skepticism of n expert, expressed before these inventors proved him wrong, is entitled to fair evidentiary weight, *see In re Piasecki* , 745 F.2d 1468, 1475, 223 USPQ 785, 790 (Fed. Cir. 1984); *In re Zeidler* , 682 F.2d 961, 966, 215 USPQ 490, 494 CCPA 1982), as are the five to six years of research that preceded the claimed invention. The evidence as a whole loes not support the PTO's conclusion that the claimed invention would have been obvious in terms of 35 U.S.C. §103.

REVERSED

- End of Case -

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